STATE OF VERMONT

SUPERIOR COURT
CHITTENDEN UNIT

CIVIL DIVISION
DOCKET NO. _____

STATE OF VERMONT,

Plaintiff,

vs.

CARDINAL HEALTH, INC. and
MCKESSON CORPORATION,

Defendants.

COMPLAINT

TABLE OF CONTENTS

The Vermont Attorney General brings this suit against Cardinal Health, Inc. and McKesson Corporation for violations of the Vermont Consumer Protection Act, negligence, and creating a public nuisance. The Attorney General seeks civil penalties, injunctive relief, disgorgement, fees and costs, and other appropriate relief.

PRELIMINARY STATEMENT

1. Over the past two decades, a public health crisis caused by prescription opioids has spread across Vermont and the entire country.

2. In Vermont, drug-related fatalities involving opioids nearly tripled between 2010 and 2018.[1]

3. Vermont ranks as the 8th-highest state in the nation for drug dependence,[2] despite other favorable health indicators like better access to health care and insurance coverage as compared to other states.[3]

4. Serious consequences radiate from every case of overdose and addiction, including harm to individuals and families and strain on the State's healthcare and social services systems. In a small state like Vermont, no case of addiction or overdose is anonymous.

5. Just the presence of prescription opioids in the State represents a risk that must be managed. Prescription opioids—including fentanyl, oxycodone, hydrocodone, and combination drugs—are controlled substances. They have a high potential for abuse and misuse; can cause serious injury, including severe psychological or physical dependence; and, therefore, are highly regulated. Equally significant, prescription opioids are subject to diversion away from legitimate

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[1] Vermont Department of Health, *Opioid-Related Fatalities Among Vermonters* (updated February 2019), http://www healthvermont.gov/sites/default/files/documents/pdf/ADAP_Data_Brief_Opioid_Related_Fatalities.pdf.
[2] amfAR Opioid & Health Indicators Database, Percent of people 12+ Reporting Drug Dependence, http://opioid.amfar.org/indicator/drugdep.
[3] *See* State Health Assessment Plan - Healthy Vermonters 2020 (December 2012), http://www healthvermont.gov/sites/default/files/documents/2016/11/Healthy%20Vermonters%202020%20Report.pdf, at 13, 5, 27.

medical, research, and scientific channels to unauthorized use and illegal sales. An inflated volume of opioids invariably leads to increased diversion and abuse. Indeed, there is a "parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and associated adverse outcomes."[4] Prescription opioids are diverted away from legitimate medical channels in a variety of ways, but the vast majority of people who misuse prescription opioids obtain their drugs (1) from friends or family members, or (2) through their own prescriptions. This means that, for most people who misuse opioids, the source of their drugs can typically be found in the excess supply of drugs in the community, beyond what is needed for legitimate medical purposes.

6. Because of the risks inherent in the distribution of prescription opioids, each of the participants in their supply chain has important legal responsibilities intended to protect against misuse and diversion of these dangerous drugs. The legal distribution of prescription opioids involves three key participants: (1) manufacturers that make the opioids; (2) distributors that supply the opioids to pharmacies; and (3) pharmacies that dispense the opioids to consumers.

7. By law, distributors—who are the gatekeepers in the prescription opioid supply chain—have strict obligations to monitor and control the sales of prescription opioids to prevent diversion.[5] The federal Drug Enforcement Administration ("DEA") recognized: "[D]istributors handle such large volumes of controlled substances and are the **first major line of defense** in the movement of legal pharmaceutical controlled substances … from legitimate channels into the

[4] Dart, Richard C., *et al.*, *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Eng. J. Med. 241 (2015).
[5] 21 U.S.C. § 823(b) (Controlled Substances Act, discussing diversion).

illicit market ...." Therefore, "it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances."[6]

8. The State brings this lawsuit against two major distributors for failing to fulfill their most fundamental legal duties in violation of Vermont statutory and common law. Cardinal Health, Inc. ("Cardinal") and McKesson Corporation ("McKesson") (collectively, Defendants) have a commanding share of the Vermont market: together they are responsible for about [redacted] of the prescription opioids distributed in the State.

9. Cardinal and McKesson violated their duties to prevent diversion by selling ever-increasing quantities of prescription opioids in Vermont and ignoring the mounting evidence that opioid sales—nationally, and within the State—were far out-pacing legitimate need. Indeed, through their willingness to uncritically supply whatever quantities of opioids pharmacies ordered, Defendants normalized overprescribing and caused widespread proliferation and availability of these dangerous drugs throughout Vermont communities. This over-supply of opioids flowed into Vermont through two primary channels. First, prescription opioids flowed unchecked into the State from Cardinal's and McKesson's excessive sales to Vermont pharmacies—far beyond what was needed for legitimate medical needs. Second, over-supply came to Vermont through illegal channels from other states, including those where "pill mills" stocked with opioids supplied by Cardinal and McKesson poured millions of prescription opioids into the black market.

10. Ultimately, Cardinal's and McKesson's inadequate systems to monitor, detect, and prevent diversion enabled the excessive sales of opioids to Vermont pharmacies. The

[6] Declaration of Joseph Rannazzisi (Deputy Administrator, DEA) at ¶ 10, *Cardinal Health, Inc. v. Holder* (D.D.C.) (No. 12-185 RBW), ECF No. 14-2, 2012 WL 11747342.

systems that Cardinal and McKesson designed were not only flawed; Defendants failed to adhere to their own flawed systems.

11. Cardinal and McKesson relied on sales-volume-based "thresholds" to detect suspicious orders (i.e., orders of unusual size, deviating substantially from a normal pattern, or of unusual frequency). These thresholds were caps set for each pharmacy's monthly opioid orders based on certain factors. If a pharmacy's order exceeded its threshold, that was an indication of potential diversion, and the Defendants were supposed to flag, stop, and investigate the order. These thresholds should have served as an important tool in detecting and preventing illegal orders. However, those thresholds were flawed in their design and implementation: not only did Defendants set them at improperly high levels, but they were also inadequately enforced.

12. Specifically, Cardinal and McKesson set the baseline thresholds far too high—permitting pharmacies to order truly excessive amounts of opioids with little or no functional safety check to catch suspicious orders. And Cardinal and McKesson routinely **increased** the thresholds or found other ways to ship the orders without conducting an appropriate investigation, canceling the order, or reporting the pharmacy to the DEA, as required by law.

13. Additionally, Cardinal and McKesson designed and implemented anti-diversion systems that were wholly inadequate and failed to satisfy their core legal duties as distributors of controlled substances. Defendants not only understaffed their anti-diversion compliance programs, but they provided inadequate training to those they employed. Moreover, Defendants inappropriately relied on front-line sales personnel to implement and enforce their anti-diversion programs. These sales personnel had a conflict of interest because their compensation structure **rewarded** increased sales. There was no compliance incentive for sales personnel to report their own pharmacy customers for placing excessive orders of opioids.

14. As a result of Cardinal's and McKesson's flawed systems, Defendants systematically failed to notify regulators about the increasing indications of widespread diversion that should have been apparent from their own distribution and sales data, as well as additional data they acquired from third-party databanks. Rather than utilizing the wealth of data they possessed to prevent and curtail the diversion of opioids, Defendants used the data to target potential customers and strategize ways to increase their market share, allowing them to profit from the rising tide of opioid misuse and abuse.

15. Cardinal's and McKesson's systematic failures to report suspicious volumes and patterns of prescription opioid sales—as they were required to do under Vermont and federal law—allowed the opioid epidemic to grow, unchecked, for years.

16. Compounding Defendants' failures to identify and prevent diversion, both companies actively engaged in marketing designed to increase the sale of opioids. Cardinal and McKesson promoted opioids to prescribers, pharmacies, and even consumers—working alongside opioid manufacturers to affirmatively **drive** the demand for prescription opioids.

17. Defendants' promotion and marketing of prescription opioids—particularly when viewed in the context of their obligations (and failures) to prevent and control diversion—constituted an unfair business practice. Through these marketing activities, Defendants echoed and reinforced the unfair and deceptive prescription opioid marketing that the drug manufacturers were disseminating through many different channels nationwide, and in Vermont. Further, some of Cardinal's and McKesson's marketing materials misrepresented the benefits of opioids or omitted the serious risks posed by opioid use. These marketing activities, together with the overwhelmingly deceptive branded and unbranded marketing that drug manufacturers disseminated through other channels, encouraged and normalized over-prescribing of

prescription opioids and effectively shifted the medical consensus regarding opioid prescribing and dispensing, nationally and in Vermont, in ways that will take years to undo.

18. Cardinal and McKesson also [redacted] the opioid manufacturers' prescription savings card programs to increase opioid sales by eliminating cost barriers otherwise associated with the initiation of brand-name opioid use. These discount programs subsidized or eliminated the out-of-pocket cost of these drugs, making them more accessible to Vermont consumers and effectively providing free or inexpensive samples of highly addictive substances. These programs also encouraged long-term use of prescription opioids—indeed, many of the savings cards had **no limit** to the number of times they could be used by the same patient—despite the fact that no good evidence existed to support long-term use of opioids.[7]

19. Cardinal and McKesson actively concealed their misconduct in failing to identify and prevent diversion and in promoting and marketing opioids. In sworn testimony, on their own websites, and in other public statements, Defendants vowed to the State and the public that their anti-diversion programs were thorough, effective, and vigorously enforced. And Defendants vowed that they had no role in influencing the prescribing or dispensing of prescription opioids and did not promote and market any pharmaceuticals—including opioids—directly to consumers. These were all false statements. The State has learned from its investigation, after reviewing documents only recently made available, that Defendants' systems to identify and report suspicious orders were seriously inadequate; that Defendants continue to misrepresent the

[7] *See* Centers for Disease Control and Prevention, Guideline for Prescribing Opioids for Chronic Pain (2016), https://www.cdc.gov/drugoverdose/prescribing/guideline.html (hereafter, "CDC Guideline"), at 2, 20, 25. (confirming, based on existing research and evidence, that opioid use presents a "serious risk" of addiction, use for three months or more "substantially increases" that risk, and there never has been "good evidence that opioids improve pain or function with long-term use").

quality, purpose, and key components of their programs; and that Defendants unfairly and deceptively marketed prescription opioids.

20. Defendants have continuously and routinely violated Vermont law, taking advantage of the dramatic rise in opioid prescribing and profiting heavily from the sale of prescription opioids that they knew, or should have known, were being diverted from the legitimate and necessary uses. The consequences have devastated the lives of many Vermonters and will reverberate in Vermont for years to come.

21. The effects of the opioid epidemic in Vermont have been profound: increased health care costs; premature death and disability; lost productivity during prime work years; increases in drug-related crime and incarceration; and the consequential devastation of households and extended families. These predictable outcomes have created a full-blown public health crisis.

22. The State now asks the Court to hold Cardinal and McKesson accountable for their conduct for the damage they have caused, the costs they have imposed on the State, and the burdens they have placed on Vermont's citizens.

PARTIES

23. Plaintiff the State of Vermont brings this action, by and through its Attorney General, Thomas J. Donovan Jr., who is authorized to represent the State in all civil matters at common law and as allowed by statute. 3 V.S.A. § 152. The Attorney General is charged with the responsibility of enforcing the Consumer Protection Act and all regulations promulgated thereunder. 9 V.S.A. § 2458.

24. The State also has standing *parens patriae* to protect the health and well-being, both physical and economic, of its residents. Opioid use and abuse have substantially affected a significant segment of the population of Vermont.

25. Defendant Cardinal Health, Inc. is an Ohio corporation with its principal place of business in Dublin, Ohio.

26. Cardinal, including its subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes pharmaceuticals, including prescription opioids, throughout the country and in Vermont. Cardinal operates 18 wholesale drug outlets that are currently licensed to conduct business in Vermont. Cardinal distributed opioids to Vermont pharmacies that were, in turn, purchased by Vermont consumers and governmental agencies. In addition to distributing opioids, Cardinal marketed and promoted opioids—including, on information and belief, in Vermont.

27. Defendant McKesson Corporation is a Delaware corporation with its principal place of business in San Francisco, California.

28. McKesson, including its subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes pharmaceuticals, including prescription opioids, throughout the country and in Vermont. McKesson operates 30 wholesale drug outlets that are currently licensed to conduct business in Vermont. McKesson distributed opioids to Vermont pharmacies that were, in turn, purchased by Vermont consumers and governmental agencies. In addition to distributing opioids, McKesson marketed and promoted opioids—including, on information and belief, in Vermont.

JURISDICTION AND VENUE

29. The State brings this action exclusively under Vermont law. The State does not assert any claims arising under federal law.

30. The Court has personal jurisdiction over Cardinal and McKesson because they regularly transacted business in Vermont, including by distributing opioids to pharmacies throughout the State; purposely directed business activities, including, on information and belief, marketing activities, into Vermont; had employees who operated in Vermont; and engaged in unlawful practices in Vermont.

31. McKesson is registered to do business in Vermont, with Corporation Service Company as its registered agent, located at 100 North Main Street, Suite 2, Barre, VT 05641. Several Cardinal affiliates and/or subsidiaries also are registered to do business in Vermont, with either Corporation Service Company, located at 100 North Main Street, Suite 2, Barre, VT 05641, or CT Corporation System, located at 17 G W Tatro Dr., Jeffersonville, VT 05464, as their registered agent.

32. Venue is proper in this Court, pursuant to 9 V.S.A. § 2458(a), because Defendants do business in Chittenden County, including distributing opioids within the county.

FACTUAL ALLEGATIONS

I. Vermont Law Imposes on Defendants a Duty to Prevent the Misuse, Abuse, and Diversion of Controlled Substances.

33. Cardinal and McKesson are licensed to distribute prescription drugs in Vermont, including prescription opioids, which are designated as controlled substances due to their high potential for abuse. A license to distribute controlled substances is valuable—it allows Defendants to participate in a tightly controlled, national market valued at more than $7 billion annually for opioids alone.

34. Distribution of controlled substances comes with a substantial duty. Distributors are obligated to take steps to provide effective controls and procedures to guard against theft and diversion of controlled substances, as a critical part of a regulatory system designed to combat drug abuse. These obligations are a crucial component of the State's efforts to protect the public health, welfare, and safety by regulating access to potentially dangerous controlled substances.

35. Vermont's common law imposes a general duty to exercise the degree of care that a reasonably prudent person / entity would exercise under similar circumstances. The scope of this duty of care is determined by the foreseeability of the consequences of the acts or omissions. It is foreseeable that distributing vast amounts of highly addictive prescription opioids into the State, while simultaneously promoting higher sales of these drugs and failing to take reasonable steps to minimize their illegitimate use, could result in widespread misuse, abuse, diversion, and serious injury.

36. Defendants acknowledge that their status as wholesale distributors of controlled substances subjects them to common law duties of care. For example, Defendants' professional lobbying association, the Healthcare Distribution Alliance ("HDA") acknowledges that distributors' responsibilities to detect and prevent diversion of controlled substances arise from the obligations that attach to "responsible members of society."[8]

37. The duty of care imposed under Vermont common law is reasonably informed by Vermont's statutes and regulations, which impose a variety of legal obligations on wholesale distributors that are designed "to promote, preserve, and protect the public health, safety, and welfare."[9]

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[8] Brief for Healthcare Distribution Alliance and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017) (No. 15-1335), ECF No. 1607110, 2016 WL 1321983 at *3.

[9] 26 V.S.A. § 2021.

38. Vermont law requires wholesale distributors to be licensed by the Vermont Board of Pharmacy (the "Board"). The Board's administrative rules impose a host of duties on wholesale distributors that are designed to protect public health and safety. To receive a license, a distributor must attest to the Board that it has implemented and will maintain a range of requirements. In particular, licensed wholesale distributors in Vermont must:

- "employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of drugs," 20-4 Vt. Code R. § 1400:17.5;
- equip their facilities with security systems suitable to protect against diversion, 20-4 Vt. Code R. § 1400:17.8; and
- adopt, maintain, and adhere to written security policies, 20-4 Vt. Code R. § 1400:17.20.

39. Vermont law also imposes duties of care on controlled substance distributors that are co-extensive with those imposed under the federal Controlled Substances Act (21 U.S.C. § 801 *et seq.*) and its implementing regulations, but that are independently enforceable under state law. Vermont law requires: (1) that distributors maintain operations "in compliance with all federal requirements applicable to wholesale drug distribution;" 26 V.S.A. § 2068(9); (2) that distributors comply with all "applicable federal, state, and local laws and rules," 20-4 Vt. Code R. § 1400:17.23; and (3) that distributors dealing in controlled substances "register with the [DEA], and .... comply with all applicable state, local, and DEA requirements," 20-4 Vt. Code R. § 1400:17.25.

40. Congress designed the federal Controlled Substances Act ("CSA") "to deal in a comprehensive fashion with the growing menace of drug abuse in the United States."[10] The CSA carries out this goal by creating a "closed system" of distribution in which every entity that

[10] 1 H.R. Rep. No. 91–1444 (1970), *as reprinted in* 1970 U.S.C.C.A.N. 4566, 4567.

handles controlled substances—including manufacturers, distributors, and dispensers—does so pursuant to a registration with the DEA.[11]

41. The distributors' role is central to the efficacy of the CSA's regulatory system. As the DEA has explained, "[b]ecause distributors handle such large volumes of controlled substances, and are the first major line of defense in the movement of legal pharmaceutical controlled substances ... from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances. Should a distributor deviate from these checks and balances, the closed system created by the CSA collapses."[12]

42. Under the CSA, a registered distributor must "provide effective controls and procedures to guard against theft and diversion of controlled substances."[13] Diversion occurs when controlled substances move out of legitimate medical, scientific, and industrial channels.[14] In Vermont, "legitimate medical channel" is narrowly defined as the possession and use by a patient of a narcotic (opioid) prescription drug in accordance with the directions of the patient's licensed health care provider, whose prescription has been dispensed by a licensed pharmacist. Any other type of dispensing,[15] possession, or use is prohibited by Vermont law[16] and thus outside a legitimate medical channel.

43. In particular, distributors must "design and operate a system to disclose to the registrant suspicious orders of controlled substances," and must report to the DEA the discovery

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[11] 21 U.S.C. §§ 821-823.
[12] Declaration of Joseph Rannazzisi (Deputy Administrator, DEA) at ¶ 10, *Cardinal Health, Inc. v. Holder* (D.D.C.) (No. 12-185 RBW), ECF No. 14-2, 2012 WL 11747342.
[13] 21 C.F.R. § 1301.71.
[14] 21 U.S.C. § 823(b).
[15] "Dispense" is defined to include "leave with" and "give away." 18 V.S.A. § 4201(7).
[16] Any possession, administering, or dispensing not specifically authorized under Chapter 84 (the Vermont controlled substances act) is prohibited by 18 V.S.A. § 4205. *See also* 18 V.S.A. § 4216.

of any suspicious orders.[17] The duty to monitor, identify, and report suspicious orders is referred to as the "Reporting Requirement."

44. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, or orders of unusual frequency.[18] This list is not exhaustive,[19] and the DEA has provided extensive guidance on the identification and reporting of suspicious orders.

45. The DEA has advised distributors that:

- they must "consider the totality of the circumstances when evaluating an order for controlled substances";[20]
- monitoring only the volume of controlled substance orders is insufficient to guard against diversion because if an order "deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious";[21] and
- signs that might be indicative that a pharmacy is engaged in diverting controlled substances, include "[o]rdering excessive quantities of a limited variety of controlled substances . . . while ordering few, if any, other drugs," and ordering controlled drugs "in quantities disproportionate to the quantity of non-controlled medications ordered."[22]

46. Defendants were aware of DEA's guidance.

47. In addition to requiring a distributor to monitor, identify, and report suspicious orders, Vermont law also requires a distributor to prevent the shipment of suspicious orders to customer pharmacies, a duty referred as the "Shipping Requirement."[23]

48. The DEA has explained the scope of the Shipping Requirement to distributors on multiple occasions.[24] Before shipping an order that has raised a suspicion, a distributor must

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[17] 21 C.F.R. § 1301.74(b).
[18] 21 C.F.R. § 1301.74(b).
[19] *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206, 221 (D.C. Cir. 2017).
[20] Letter from Joseph T. Rannazzisi, Deputy Administrator, DEA to Cardinal Health, Inc. (Sept. 26, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 12-185 RBW (D.D.C.) (Dkt. No. 14-51).
[21] Letter from Joseph T. Rannazzisi, Deputy Administrator, DEA to Cardinal Health, Inc. (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 12-185 RBW (D.D.C.) (Dkt. No. 14-8).
[22] Letter from Joseph T. Rannazzisi, Deputy Administrator, DEA to Cardinal Health, Inc. (Sept. 26, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 12-185 RBW (D.D.C.) (Dkt. No. 14-51).
[23] *Masters*, 861 F.3d at 222.

"conduct an independent analysis ... to determine whether the controlled substances are likely to be diverted from legitimate channels."[25] That independent analysis must be thorough and must include certain steps, including: (1) requesting information from the pharmacy that placed the order; (2) documenting the pharmacy's explanation for the order; and (3) engaging in any additional follow-up necessary to determine the legitimacy of the order.[26] The independent investigation must be sufficient to dispel all of the red flags that gave rise to the suspicion.[27]

49. Even the HDA, Defendants' lobbying organization, expressly acknowledged the Shipping Requirement in 2008, where it advised distributors that they "should not ship to the customer any units" of a potentially suspicious order without conducting a "fully documented" investigation to determine whether the order is legitimate.[28]

II. Defendants Violated Their Obligations to Prevent the Misuse, Abuse, and Diversion of Prescription Opioids.

50. Despite their duty to prevent the diversion of opioid drugs, neither Cardinal nor McKesson attempted to create formal anti-diversion programs to fulfill their duty until 2007. And even then, the programs they designed failed to meet their legal obligations to detect, prevent, and report diversion. Defendants also failed to fully implement these anti-diversion programs, rendering them both deficient on their face and unenforced in practice.

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[24] *See, e.g.*, *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01, 36,500 (DEA July 3, 2007) (holding that a distributor violated its duty by shipping suspicious orders without first conducting a due diligence investigation); Letter from Joseph T. Rannazzisi, Deputy Administrator, DEA to Cardinal Health, Inc. (Sept. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 12-185 RBW (D.D.C.) (Dkt. No. 14-51) (providing that a distributor must "exercise due care in confirming the legitimacy of all orders prior to filling").

[25] Letter from Joseph T. Rannazzisi, Deputy Administrator, DEA to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health, Inc. v. Holder*, No. 12-185 RBW (D.D.C.) (Dkt. No. 14-8).

[26] *Masters Pharm., Inc.*, 861 F.3d at 212-13.

[27] *Masters Pharm., Inc.*, 861 F.3d at 212-13.

[28] *HDA Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, available as Attachment 1 to "Prescription Drug Diversion: Combatting the Scourge," Hearing before the Subcommittee on Commerce, Manufacturing & Trade of the U.S. House of Representatives Committee on Energy and Commerce (112th Cong., 2d Session) (March 1, 2012) at 216, 227, 230 (hereinafter "HDMA Industry Compliance Guidelines"), available at https://archive.org/details/gov.gpo.fdsys.CHRG-112hhrg80861.

51. Cardinal and McKesson each designed anti-diversion programs that allowed them to continue shipping ever-increasing and excessive quantities of opioids into Vermont without conducting the required due diligence into their pharmacy customers or notifying law enforcement of ordering volumes and patterns that were indicative of diversion.

52. Both Defendants' anti-diversion programs relied on monthly, volume-based order "thresholds" for each pharmacy customer as the purported trigger for identifying potentially suspicious orders. Their systems failed to identify all orders of unusual size, frequency, and pattern, in violation of Defendants' duties to identify, report, and prevent shipment of all suspicious orders.

53. Cardinal and McKesson each designed and implemented their anti-diversion programs in a way that manipulated and reduced the likelihood of "threshold events," which in turn allowed them to avoid conducting appropriate investigations of their pharmacy customers. Defendants were motivated to minimize threshold events because they wanted to avoid losing customers.

54. Cardinal and McKesson pumped unwarranted volumes of prescription opioids into Vermont, disregarding the obvious signs that diversion was occurring and that a serious health crisis was developing. Based on information currently available to the State, McKesson shipped [redacted] of opioids into Vermont from [redacted] That is equivalent to more than [redacted] prescription opioid pills for every man, woman, and child in the State. Based on the same data, Cardinal shipped [redacted] of opioids into Vermont during the same time frame, equivalent to about [redacted] opioid pills for every man, woman, and child in the State.

55. Defendants' failure to create and implement effective anti-diversion programs, in violation of their duty under Vermont law, resulted in the distribution of excessive quantities of dangerous and addictive prescription opioids into Vermont, facilitating an epidemic of opioid abuse, misuse, and diversion that was both foreseeable and inevitable.

A. Cardinal designed a monitoring system that failed to monitor, identify, report, and prevent the fulfillment of suspicious orders.

56. Following a series of investigations in 2006 and 2007 by state and federal law enforcement into Cardinal's anti-diversion monitoring practices, *see infra* at Part V.A, Cardinal created an anti-diversion program that purported to monitor, identify, report, and prevent the shipment of suspicious controlled substance orders. The main components of Cardinal's program purported to include:

- conducting a due diligence review before onboarding new pharmacy customers;
- setting thresholds, or order limits, to restrict the number / volume of opioids a pharmacy could order each month;
- utilizing an electronic system to hold orders that exceeded thresholds, termed "threshold events," pending further review by Cardinal's anti-diversion staff; and
- conducting regular site visits of existing customers to uncover evidence of suspicious activity.

57. In actuality, Cardinal's four-pronged system was designed to ensure that its pharmacy customers would receive a steady stream of opioids and that anti-diversion duties would never interfere with the Cardinal's bottom line.

1. Cardinal's due diligence policies for onboarding new pharmacy customers were facially inadequate.

58. Cardinal's anti-diversion policy required review of potential new pharmacy customers before onboarding them to ensure that customers purchasing opioids from Cardinal were not engaged in diversion. However, Cardinal's customer onboarding policies were

inadequate because they did not allow Cardinal to independently assess a pharmacy's risk of diversion.

59. From approximately December 2007 through 2012, Cardinal's process for approving new pharmacy customers seeking to order opioids was limited to (1) receiving a customer survey with basic information about the pharmacy's business; (2) receiving an agreement signed by the pharmacy pledging compliance with DEA regulations; and (3) confirming that the pharmacy and its employees were registered with the DEA and relevant state regulatory entities.

60. As written, Cardinal's policies were insufficient to determine whether new pharmacy customers were involved in diversion. Those policies provided Cardinal's sales representatives—[redacted]—with responsibility for collecting relevant documents and completing the survey for the customer. Cardinal did not require an independent inquiry into whether other distributors were providing controlled substances to the pharmacy, nor did it require the pharmacy to provide [redacted] preventing Cardinal from [redacted] Cardinal also did not require site visits at a new pharmacy customer before beginning to ship opioid drugs to it, further evidence of Cardinal's failure to fulfill its broader duty to guard against diversion.

61. To this day, Cardinal's new customer approval review policy relies [redacted] Cardinal still does not [redacted]

[redacted] These inadequacies prevent Cardinal from ensuring the legitimacy of controlled substance purchases by new pharmacy customers.

2. Unreasonably high "thresholds" made it possible for Cardinal to avoid identifying and reporting suspicious orders.

62. Cardinal's suspicious order monitoring system relied on thresholds to identify opioid orders that required review. But Cardinal relied on unreasonably high thresholds, which minimized the number of flagged orders, and allowed Cardinal to avoid investigating or reporting its pharmacy customers when they placed ever-increasing or otherwise suspicious orders for opioids.

63. Cardinal designed its system so that, if an opioid order exceeded a pharmacy's pre-set monthly threshold limit, the order would be held pending review. Moreover, under Cardinal's system, subsequent orders of opioids in the same drug family (i.e., opioids sharing the same narcotic ingredient) also were supposed to be held pending review, interrupting the pharmacy's supply of all opioids in that drug family.[29]

64. However, Cardinal systematically set thresholds at inappropriately high levels to minimize the number of threshold events, to avoid order delays, and to prevent disruption of Cardinal's revenue stream and pharmacy customer satisfaction. Cardinal (1) used unreasonably high sales figures to set thresholds, (2) allowed chain pharmacies with their own anti-diversion programs to have even *higher* thresholds; and (3) set thresholds without accounting for critical factors that the DEA had explained it was required to consider and that would have allowed Cardinal to detect diversion.

65. Fearing that any [redacted] Cardinal set its thresholds at unreasonably high levels from approximately December 2007 through 2012.

[29] For example, OxyContin and Percocet are in the same drug family with generic oxycodone, while hydrocodone is a different drug family.

66. Cardinal categorized pharmacy customers based on order volume (small, medium, and large) and business class (e.g., retail pharmacies, hospitals, and long-term care facilities). Cardinal then averaged the monthly quantity of each opioid drug family [redacted] for a given pharmacy size and type, and then **tripled** the monthly average to create the threshold amount. Cardinal's thresholds thus allowed its pharmacy customers to order **three times** the average volume of opioid drugs ordered by pharmacies of similar size and type before triggering any suspicious order review.

67. Moreover, the averages on which Cardinal relied were inflated even before Cardinal tripled them to set the final thresholds. As the baseline for its thresholds, [redacted]—a time period during which opioid sales, and diversion of opioids to non-medical use, were already at dangerously excessive levels. In 2007, for example, pharmacies dispensed 228.43 million opioid prescriptions nationwide—at the time, the highest number ever recorded—equivalent to 75.9 prescriptions per 100 persons and a 243% percent increase compared to opioid prescription levels in 1996, the year OxyContin ER, an extended release formulation of oxycodone, was launched with an aggressive marketing campaign. In 2008, opioid prescribing increased further, reaching 78.2 prescriptions per 100 persons.

68. From approximately December 2007 through 2012, Cardinal's system granted even higher thresholds to pharmacies that maintained their own anti-diversion or loss-prevention programs. Cardinal permitted these higher thresholds based on the flawed premise [redacted][30] which ignores and abdicates Cardinal's own independent duty to identify and report suspicious orders and guard against diversion.

[30] CAH_MDL2804_02953792 at 3–4.

69. [redacted] Cardinal's oxycodone thresholds for [redacted] Cardinal justified the disproportionate thresholds at these pharmacies on the theory that the hospitals or other institutions they serve [redacted][31] Yet Cardinal acknowledged that [redacted]. Through these inflated thresholds, Cardinal ensured that Vermont pharmacies would not trigger a threshold event, even if they ordered significantly greater-than-usual volumes of opioids.

70. Only when confronted with enforcement actions by the DEA and DOJ in 2012, *see infra* at Part V.A, [redacted], making clear just how inflated Cardinal's threshold formulas had been previously. For example, [redacted] in Chittenden County, Vermont [redacted]

[31] CAH_MDL2804_01891921 at 4, 8.

[redacted]

71. Additionally, Cardinal's threshold calculations failed to incorporate critical factors necessary to make the thresholds a meaningful tool for monitoring suspicious orders. Despite the DEA's guidance that a suspicious order monitoring system should account for factors including the geographic location of its pharmacy customers, Cardinal's thresholds have never accounted for the size or demographics of the population served by a pharmacy, nor the total number of pharmacies within the same service area.

72. From approximately December 2007 through 2012, Cardinal's thresholds also did not account for the possibility that pharmacies were receiving opioids from multiple distributors. Cardinal also sometimes set its thresholds without considering pharmacies' actual prescription volumes. If a retail independent pharmacy did not provide Cardinal with its dispensing data, Cardinal automatically provided the pharmacy with generic "mid-level" threshold limits rather than demand the information or conduct an investigation. Cardinal did this to [redacted]

73. Cardinal's thresholds for chain pharmacies—retail pharmacies owned by a common parent company and operating under the same name with multiple locations—were based on a standard threshold for the entire chain. Thus, a pharmacy serving a small community in Vermont, or that had a minimal opioid portfolio, could nevertheless be permitted to order unnecessarily large quantities of opioids merely because that pharmacy was part of a retail pharmacy chain. In one instance, [redacted]

[redacted] Windham County, Vermont [redacted]

[redacted]

74. Throughout the entire period from approximately December 2007 to the present, Cardinal's thresholds have failed to account for the quantity of opioids distributed and dispensed in a given geographic region. Despite easily accessible state and regional (1) distribution data, (2) prescribing data, (3) market share data, and (4) population data, some of which is also available at the county- and census tract-level, and all of which [redacted] [redacted] see *infra* Section IV.B, Cardinal's thresholds did not account for opioid distribution, opioid prescribing, its own market share, or the population of a given geographic area. Cardinal failed to [redacted]

75. Because of these fundamental design flaws and Cardinal's exclusive reliance on volume-based thresholds to trigger investigation of orders, Cardinal's threshold-based system has been ineffective at identifying suspicious orders. From approximately December 2007 to the present, Cardinal's system has relied exclusively on these thresholds to trigger investigation of pharmacy orders. Cardinal's monitoring system was originally "primarily focused on volume," and even after Cardinal began considering additional factors in 2011—pharmacy ordering patterns and frequency—Cardinal only reviewed those factors when an investigation of an order was "triggered" by exceedance of the volume-based threshold. By design, this system is too simplistic for Cardinal to reliably identify orders that are potentially suspicious for other reasons, such as unusual frequency or pattern.

76. Because of the flaws in Cardinal's design of—and exclusive reliance on—these improperly high volume-based thresholds, Cardinal's suspicious order monitoring system was and is insufficient to identify, review, and report suspicious orders as Cardinal is required to do under applicable law.

3. Cardinal manipulated its policies to help pharmacies prevent threshold events.

77. Cardinal has been aware of [redacted] From approximately December 2007 through 2012, Cardinal's official policy was to not disclose specific threshold levels to pharmacies. However, Cardinal also wanted to prevent threshold events from occurring.

78. Thus, without disclosing a specific threshold to a pharmacy, Cardinal would: (1) alert pharmacies when they were approaching their thresholds, thereby allowing the pharmacies to request a preemptive threshold increase; (2) coach pharmacies on how to avoid triggering review of their orders; and (3) raise thresholds without conducting any investigation into the pharmacy's operations.

79. While in the earliest stages of [redacted] To meet this need, from approximately December 2008 through 2012, Cardinal tracked pharmacies' proximity to their thresholds—their "threshold accrual"—and used an "early dialogue" process, in which sales representatives were required to [redacted] a pharmacy when the pharmacy's controlled substance orders reached a certain percentage of its threshold. [redacted]

[redacted][32] this process directly subverted the very purpose of the thresholds—alerting Cardinal to potentially suspicious orders. Instead, Cardinal warned pharmacies when they were approaching a potential threshold event so that the pharmacy could request—and Cardinal could grant—a preemptive increase. Cardinal was extremely successful in shielding itself and its pharmacy customers from threshold events: from 2010 to 2011—the first year of the early dialogue intervention program—threshold events dropped by 37%.

80. After 2012, Cardinal became even more aggressive about helping pharmacies to avoid threshold events and evade review. From approximately [redacted] to [redacted][33] Sales representatives had multiple tools available to review a pharmacy customer's thresholds and accruals, [redacted][34]

81. Further undermining the threshold system, Cardinal's [redacted]

[32] CAH_MDL2804_02246162 at -197.
[33] CAH_MDL2804_02011099.
[34] Deposition of Todd Cameron, Sept. 26, 2018, CAH_MDL2804_02953369, at 295:5–22.

[redacted][35] Pharmacies selected [redacted] However, instead of [redacted] Cardinal's anti-diversion investigator [redacted]

82. [redacted]

83. Even after Cardinal finally did implement [redacted] it continued to [redacted] For example, the policy [redacted]

[35] CAH_MDL2804_00035120 at 1.

[redacted] Cardinal's policy also allows [redacted]

4. Cardinal avoided adequately investigating, blocking, and reporting orders triggered by threshold events.

84. Cardinal designed its suspicious order monitoring system so that when a pharmacy did place an order exceeding a threshold—indicating that the order was potentially suspicious and required further review—Cardinal could resume normal shipments to that pharmacy as quickly as possible. To that end, Cardinal (1) gave pharmacies [redacted] [redacted] (2) required minimal due diligence before fulfilling held orders; (3) allowed pharmacies that exceeded a threshold for one opioid drug family to continue ordering opioids from other drug families; and (4) used a monthly accrual period, [redacted] [redacted] Finally, even when Cardinal determined that an order was "unreasonable" and should not be shipped, Cardinal (5) failed to report all such orders to the DEA, as required by law.

85. From approximately 2013 to the present, [redacted]

[redacted]

86. When Cardinal did hold a pharmacy's order pending review, Cardinal failed to conduct adequate due diligence to determine whether to cancel the order and report it as suspicious or to release and ship the order. From approximately December 2007 through 2012, Cardinal's diligence review was limited to an online survey completed by the pharmacy responsible for the potentially suspicious order; a "customer profile" that included only basic information about the pharmacy and its opioid drug purchases; and the held order itself. Cardinal did not require a site investigation before releasing an order that exceeded a threshold, [redacted]

87. From approximately 2013 to the present, [redacted]

88. Cardinal's suspicious order monitoring system also failed to ensure adequate investigation of orders flagged as potentially suspicious by Cardinal's distribution center employees. Cardinal labeled these potentially suspicious orders as "orders of interest." From approximately December 2007 through 2012, Cardinal allowed distribution center supervisors, "based upon [their] knowledge and experience," to release these orders of interest without any

further review, oversight, or documentation.[36] Only if the supervisor, in his or her sole discretion, decided to hold the order would the order be subject to review by Cardinal's anti-diversion department.

89. Cardinal also designed its thresholds so that "threshold events"—and any resulting hold and investigation of a pharmacy's order—would have as little impact as possible on the pharmacy's ability to continue ordering opioids. From approximately December 2007 to [redacted], Cardinal has set separate thresholds for each drug family, and following a threshold event, only holds orders for drugs in the specific drug family with the threshold exceedance. The logical result of this policy is that a threshold event in one drug family does not impact or interrupt a shipment of opioids belonging to another drug family, despite the indication that the pharmacy could be a source of opioid diversion. [redacted]

90. From approximately December 2007 to [redacted], Cardinal's monthly threshold levels reset with each new monthly accrual period—without accounting for suspicious ordering activity that occurred in the preceding accrual period. This means that pharmacies [redacted]

91. From approximately December 2007 through 2012, Cardinal also failed to appropriately report suspicious orders to the DEA. Under Cardinal's policy, an employee reviewing a threshold event had the authority to decide whether the excessive order was

[36] Investigation Report of the Special Demand Committee, Board of Directors of Cardinal Health (Apr. 12, 2013) at 15, https://www.cardinalhealth.com/content/dam/corp/web/documents/Report/CH-Report-of-Special-Demand-Committee-April-12-2013-Redacted.pdf

"reasonable" or "unreasonable." Cardinal's policy gave little guidance as to what orders were "reasonable," specifying only that a reviewer should use "applied reasoning" and offering several general factors for consideration, including "seasonal events, natural events, [and] regional prescribing habits." Even though an excessive and unreasonable order would certainly meet the definition of "suspicious" under the controlling regulations, Cardinal would still not report those orders to the DEA unless a Cardinal reviewer also designated those orders as suspicious at the reviewer's own discretion. By building this discretionary process into its anti-diversion system, Cardinal allowed its personnel to limit the number of "suspicious orders" they reported to the DEA, even when those orders were flagged by Cardinal's system because they bore all the hallmarks of a "suspicious order."

5. Cardinal's sales representatives conducted the majority of site visits, and Cardinal's investigators deferred to the pharmacies they were investigating.

92. Many indicators of diversion, including those listed in Cardinal's policies governing on-site investigations of its pharmacy customers, cannot be identified through electronic order monitoring alone. Thus, a critical component of Cardinal's duty was to conduct regular due diligence reviews of its pharmacy customers, including regular on-site visits, to monitor for and guard against diversion. Despite this, Cardinal relied on threshold events to trigger most site visits. Moreover, Cardinal (1) placed most of the responsibility for conducting site visits on its sales force; and (2) required that its investigators defer to the pharmacies supposedly under investigation.

93. Cardinal's anti-diversion program relies heavily on its sales force—rather than compliance personnel—to investigate the sales employees' own pharmacy customers. The

Cardinal sales force is treated as the company's [redacted]

94. Cardinal's sales employees look for the more extreme indicators of diversion including long lines, minimal front-end merchandise, and out-of-state license plates in the parking lot. But, from at least June 2009 to March 2013, sales employees only were required to report pharmacy customers that exhibited "two or more" of these indicators, thus allowing Cardinal to continue selling opioids to pharmacies that exhibited suspicious activity without further investigation.

95. From approximately December 2008 through May 2013, Cardinal's sales force monitored pharmacy customers using monthly "Highlight Reports" that identified pharmacies based on increases in their opioid drugs orders. [redacted][37]—rather than as a way to identify customers placing potentially suspicious orders. Where pharmacies had extreme increases in opioid sales—over 15 percent per month—sales employees visited the pharmacies to assess the pharmacy for visible signs of diversion. But where pharmacies had increases in their opioid sales of between 10 and 15 percent, sales employees merely were required to call the pharmacy "to understand the reason for the increased ordering."[38] Unless the pharmacy requested a threshold increase or the salesperson reported outward signs of diversion, no further action was taken. [redacted]

[37] *See* CAH_MDL2804_02954214 at 4; Deposition of Jennifer R. Norris, Aug. 7, 2018, CAH_MULTISTATE_0014000, at 269:8–22; CAH_MDL2804_02954268 at 3.

[38] Investigation Report of the Special Demand Committee, Board of Directors of Cardinal Health (Apr. 12, 2013) at 13, https://www.cardinalhealth.com/content/dam/corp/web/documents/Report/CH-Report-of-Special-Demand-Committee-April-12-2013-Redacted.pdf.

96. Cardinal's sales employees' anti-diversion duties conflicted with their compensation incentives. Cardinal expected its sales employees to [redacted] [39] Reporting a pharmacy as a diversion risk could damage a sales representative's relationship with the pharmacy customer, potentially reducing the sales representative's ability to increase sales to that pharmacy. Cardinal also gave sales representatives [redacted], leaving little doubt as to where sales representatives were incentivized to direct their focus and time.

97. When Cardinal did conduct full site visits using anti-diversion investigators, those visits [redacted] [40] [redacted]

B. Cardinal failed to adhere to the terms of its own anti-diversion program.

98. Not only did Cardinal design a seriously deficient anti-diversion program, it also failed to adhere to it. The company consistently has understaffed its anti-diversion department, raised pharmacy thresholds without enough scrutiny of factors relevant to potential diversion, and failed to report or otherwise diligently investigate all orders that exceeded a set threshold. Cardinal also allowed large chain pharmacies to operate independently, under their own set of rules—often by allowing chain pharmacies to carry out their own investigations of suspicious orders with no oversight from Cardinal. In each of these ways, Cardinal undermined its already-

[39] CAH_MDL2804_00618377 at 5, 9.
[40] CAH_MDL2804_02904365, at -380.

ineffective anti-diversion program, violating its legal duties and resulting in increasing and undetected diversion of opioids.

1. Cardinal understaffed its anti-diversion department.

99. Wholesale distributors of controlled substances have a duty under Vermont common law, statutes, and regulations to "employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of drugs." 20-4 Vt. Code R. § 1400:17.5. Cardinal breached that duty by failing to staff enough well-trained individuals on its anti-diversion team.

100. Despite having [redacted] distinct pharmacy customers that order controlled substances nationwide—[redacted] of which order opioid drugs—Cardinal employed only **two people** devoted to anti-diversion prior to 2007. Following the DEA's 2007 enforcement action against Cardinal, it increased the anti-diversion group, initially hiring 24 compliance officers. These compliance officers, however, were not responsible for analyzing threshold events or investigating pharmacies, but instead were tasked with "various compliance measures" that applied specifically to distribution centers, [redacted] By 2014, there were only around [redacted] employees responsible for these compliance functions.

101. Cardinal's failure to staff a sufficient number of properly trained investigators prevented it from conducting necessary investigations of its pharmacy customers. [redacted]

[redacted]

102. [redacted]

103. These staffing failures have had real-world consequences in Vermont. Cardinal's internal documents confirm that, [redacted] Vermont retail pharmacy customers [redacted] in Chittenden County, Vermont and [redacted] in Franklin County, [redacted] Vermont [redacted]

2. Cardinal raised thresholds, failed to report flagged orders, and shipped orders, without conducting a diligent investigation.

104. Cardinal has admitted that it did not report all suspicious orders of controlled substances to the DEA. For example, from approximately December 2007 through 2012, Cardinal only reported orders that were so egregious that they led Cardinal to terminate a pharmacy's ability to order controlled substances altogether. Under this system, Cardinal's Massachusetts distribution center, which services Vermont, [redacted]

[redacted] Cardinal filled more than [redacted] opioid orders in Vermont, [redacted] In fiscal year 2011, Cardinal reported just 47 total suspicious orders to the DEA from its 24 distribution centers **nationwide**. That same year, Vermont's opioid-related overdose death rate reached 9.1 deaths per 100,000 persons, nearly triple the rate it had been in 2000; that rate has since doubled again, rising to 18.4 deaths per 100,000 persons in 2016, the most recent year for which data are available.[41]

105. On several occasions, Cardinal shipped suspicious opioid orders to Vermont pharmacies without conducting any investigation and without reporting the suspicious orders to the DEA in direct violation of its duty under Vermont law. For example, [redacted] Lamoille County, Vermont, [redacted] In violation of Cardinal's duty, this notation provides no indication of whether Cardinal visited or otherwise contacted the pharmacy to inquire about these orders; whether the pharmacy provided any response that would justify the threshold events; or whether Cardinal engaged in any form of investigation whatsoever to ensure the legitimacy of these orders.

106. [redacted] Franklin County, Vermont [redacted]

[41] NIDA, Vermont Opioid Summary (Revised March 2018), https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/vermont-opioid-summary (Filesite # 2471068)

[redacted][42][redacted][43] The cursory notations contained in these files similarly provide no indication that Cardinal ever conducted any form of investigation to determine the legitimacy of the orders, as required under Vermont law.

107. In some cases, Cardinal responded to an order that exceeded a threshold by improperly and [redacted]

108. For example, in [redacted], Cardinal's monitoring system [redacted] Chittenden County, Vermont [redacted]

[42] CAH_MULTISTATE_0008706.
[43] CAH_MDL2804_00539890

[redacted]

[redacted][44] These notations are conclusory; they provide no indication of whether Cardinal contacted the pharmacy, received a response, or engaged in any other manner of investigation to ensure the legitimacy of the order or the need for a threshold increase, in violation of Cardinal's duty under the law.

109. In other instances, when an order would have exceeded a threshold, [redacted]

110. For example, [redacted] Rutland County, Vermont [redacted]

[44] CAH_MULTISTATE_0008706.

[redacted]

111. Cardinal's failure to report or sufficiently investigate these orders is particularly egregious considering this pharmacy's pattern of placing suspicious orders for controlled substances. [redacted]

112. [redacted][45] [redacted]

[45] CAH_MDL2804_00551310.

[redacted]

113. In some instances, Cardinal's failure to report suspicious orders resulted from [redacted] Vermon [redacted][46]

114. In all, an initial review of data derived from Cardinal's suspicious order monitoring system indicates that, [redacted]

3. Cardinal filled pharmacy orders for opioids after it had already identified related orders as suspicious.

115. On several occasions, Cardinal violated its duty under Vermont law by cancelling (also referred to as "cutting") an order that exceeded a threshold and allowing the pharmacy to place a subsequent, often smaller order for the same drug family (that would not trigger a threshold event). [redacted]

[46] CAH_MDL2804_02101802.

[redacted]

116. [redacted]

117. Cardinal engaged in this practice in Vermont. For example, [redacted] in Rutland County, Vermont [redacted]

4. Cardinal applied a different, even looser, set of rules to its chain pharmacy customers.

118. Cardinal did not independently investigate potentially suspicious orders by "chain pharmacies"—retail pharmacies owned by a common parent company and operating under the same name with multiple locations. Instead, when a chain pharmacy hit a threshold, Cardinal merely asked the chain pharmacy's corporate headquarters for an explanation. Cardinal relied

entirely on the corporate office's response, conducted no investigation of its own, and did not even make contact with the individual pharmacy in the chain that placed the potentially suspicious order.

119. Cardinal cannot abdicate its anti-diversion duties by delegating them to another player in the opioid distribution chain. To the contrary, Cardinal's duty to prevent diversion exists regardless of whether its customers are small, independent pharmacies or part of a large chain. As early as 2009, the DEA specifically admonished Cardinal for treating chain pharmacies differently from independent pharmacies. During a DEA review of Cardinal's Massachusetts distribution center, which ships prescription opioids into Vermont, Cardinal was unable to produce any diligence files for its chain pharmacy customers. When the DEA pressed Cardinal for the reason no diligence files existed for these pharmacies, Cardinal admitted that it was because the investigation of suspicious orders was delegated to the chain pharmacy's corporate headquarters and that Cardinal did not undertake any independent investigation of the conduct. The DEA told them at the time that "due diligence investigations must be performed on all customers, chain pharmacies included," and that those due diligence responsibilities included site visits.[47]

120. Since at least 2009 through approximately 2012, Cardinal continued to exempt its chain pharmacy customers from Cardinal's monitoring programs and instead relied on them to investigate and report their own suspicious activity. In doing so, Cardinal abdicated one of its core legal duties, and improperly relied on chain pharmacies to investigate and report their own suspicious activity—something that creates an obvious conflict and is improper on its face.

[47] Decl. of Joseph Rannazzisi, Deputy Administrator, DEA ¶ 59 (Feb. 10, 2012), filed in *Cardinal Health v. Holder*, 12-cv-00185-RBW (D.D.C.) (Dkt. No. 14-2).

121. In instances where a chain pharmacy placed an order that resulted in a threshold event, Cardinal's policy was **not** to conduct a site visit and **not** to contact the specific pharmacy that had placed the potentially-suspicious order. Instead, Cardinal's protocol was to contact only the corporate headquarters of the pharmacy chain and then permit the chain's headquarters to supply information about the held order without Cardinal taking steps to independently verify the information provided by the pharmacy's corporate headquarters.

122. Cardinal's internal policies even permitted **permanent threshold increases** for a specific pharmacy based solely on the explanation proffered provided by the pharmacy's corporate headquarters. Prior to May 14, 2012, Cardinal failed to conduct **any** site visits at any of its large chain pharmacy customers.

123. Cardinal's differential treatment of its chain pharmacy customers also extended to its new customer on-boarding process. Cardinal's on-boarding process for new, independent pharmacies included collecting a variety of "know your customer" data, including whether the pharmacy filled prescriptions for out-of-state patients, the pharmacy's expected usage for certain products, and whether there were local pain clinics in proximity to the pharmacy. In contrast, for new chain pharmacy customers, Cardinal collected only information about the chain's number of stores, anticipated drug usages, and internal diversion programs. Cardinal's failure to gather and maintain this know-your-customer data prevented it from being able to determine accurately whether orders placed at specific chain pharmacies might be suspicious or otherwise prone to diversion.

124. By employing a less rigorous onboarding process for chain pharmacies and by allowing its chain pharmacy customers to conduct their own suspicious order investigations,

Cardinal was able to appease its largest customers and continue shipping excessive quantities of opioids into Vermont without interruption.

C. McKesson designed a monitoring system that failed to monitor, identify, report, and prevent the fulfillment of suspicious orders.

125. As first referenced in Section II, McKesson failed to design an anti-diversion program to fulfill its obligations under Vermont law to detect, prevent, and report diversion. McKesson's anti-diversion program did not require adequate due diligence of new pharmacy customers; set artificially high thresholds based on poor data and metrics; proactively informed pharmacy customers of their thresholds to avoid investigations; and permitted threshold manipulation to support increased opioid sales.

126. In addition to its poor design, McKesson failed to even fully implement the inadequate components of its program, as discussed in Section D below. Consequently, McKesson's anti-diversion program, like Cardinal's, was both poorly designed and unenforced in practice.

1. Overview of McKesson's Controlled Substance Monitoring Program

127. In response to a 2008 settlement agreement with the DEA and DOJ, McKesson created an anti-diversion program called the Controlled Substance Monitoring Program ("CSMP"). McKesson's CSMP was supposed to implement the following components: (1) due diligence procedures for onboarding new pharmacy customers and monitoring existing customers; (2) maximum monthly threshold limits, or order limits, on the amount of prescription opioids available to pharmacy customers; (3) and a three-tiered investigatory and reporting process to identify and report suspicious orders of prescription opioids that exceeded these thresholds.

128. The CSMP's three-tiered investigatory procedures were supposed to be triggered by an order that exceeded a threshold. During the initial investigation of an excessive order, termed a Level 1 review, McKesson was supposed to contact the pharmacy customer to determine the reason for the excessive order, and conduct additional analysis and investigation, such as reviewing the pharmacy customer's sales patterns. If the Level 1 review indicated that the opioid order was "reasonable," the pharmacy could obtain approval for a threshold increase. If the Level 1 review was not "conclusive," the CSMP required two more levels of investigation by various McKesson personnel before deeming the order suspicious and reporting it to the DEA. **It was only after a Level 3 review that the order was deemed "suspicious" and was supposed to be reported to the DEA.**

129. To administer and oversee the CSMP in 2008, McKesson appointed one Director of Regulatory Affairs ("DRAs") for [redacted] The DRAs' duties included approving new pharmacy customers, approving threshold increase requests, and overseeing and conducting investigations of existing pharmacy customers.

130. Sales personnel and Distribution Center Managers were also charged with core anti-diversion responsibilities, including gathering information, conducting diligence investigations, and reporting suspicious activity, [redacted]

2. Due diligence policies for onboarding new pharmacy customers were facially inadequate.

131. Under the first component of the CSMP, McKesson was supposed to investigate new pharmacy customers before supplying them with prescription opioids. However, the design

of McKesson's customer onboarding procedures under the CSMP were inadequate to determine whether a pharmacy presented a risk of diversion.

132. First, McKesson's sales representatives, who had a financial incentive to [redacted] However, the questionnaire used by these sales representatives contains no [redacted] In addition, McKesson improperly [redacted]

133. McKesson also routinely failed to adhere to these procedures. For example, a [redacted]

134. McKesson's onboarding policies were even more lax for its largest chain pharmacy customers. In fact, the CSMP only requires an [redacted]

3. Unreasonably high threshold levels shielded McKesson from identifying and reporting suspicious orders.

135. The intended purpose of McKesson's threshold system, the second component of the CSMP, was to provide an "automatic block" to prevent pharmacy customers from obtaining opioids in an amount that exceeded their monthly limit. An order that exceeded the limit, and that was subsequently blocked, was sometimes termed a threshold event, [redacted] or "incursion" by McKesson. Under the CSMP, a pharmacy customer's order could be unblocked after it exceeded a threshold only if: (1) [redacted] (2) [redacted] or (3) [redacted] thereby allowing the pharmacy to once again start from zero and purchase up to the threshold limit.

136. Although thresholds were the cornerstone of the CSMP, from 2008 through 2013 McKesson routinely used improper metrics and set thresholds at artificially high levels. To assign thresholds in 2008, McKesson first calculated [redacted] Yet as discussed above, 2007 and 2008 were years that set records for opioid overprescribing. During the same time frame—in 2008—McKesson entered into an agreement with the DEA and DOJ to settle claims based on its failure to monitor and report suspicious orders across the country. Nevertheless, [redacted] On top of these inflated amounts, McKesson's threshold-setting procedures also [redacted]

Further, McKesson retained discretion to [redacted]

137. In addition, from at least [redacted] through [redacted], McKesson's thresholds did not [redacted]

138. These artificially high thresholds thwarted the CSMP's ability to monitor and identify suspicious orders in Vermont. For example, in [redacted] From [redacted] through [redacted] By consistently setting thresholds well above a pharmacy's typical monthly ordering quantity, pharmacies did not exceed their thresholds unless they ordered many multiples of prescription opioids over their monthly averages, and McKesson's pharmacy customers were able to place unusually large and suspicious orders without triggering any investigation or review.

139. Only after significant pressure from the DEA and DOJ in 2014 did McKesson begin implementing [redacted] demonstrating how inflated those pharmacies' previous thresholds had been. For example, [redacted]

[redacted]

140. Even after 2014, McKesson suggested that it continue using certain previous threshold metrics for its largest chain pharmacy customers. For example, in [redacted] [48]

4. McKesson's CSMP permitted advance warnings and inappropriate disclosures to pharmacy customers that they were approaching their monthly thresholds.

141. Although McKesson's CSMP mandated that [redacted] As one employee explained in designing this loophole, [redacted]

142. Similarly, McKesson wanted to provide assurances to pharmacy customers that the threshold system would not get in the way of sales. For example, McKesson employees discussed their concern about [redacted]

[48] MCK-AGMS-032-0003426.
[49] MCK-AGMS-035-0001696.

[redacted][50]

143. Unsurprisingly, this loophole was written directly into the CSMP manual, which noted that [redacted] The CSMP manual also stated [redacted][51]

144. McKesson permitted pharmacies to request a permanent or temporary increase in their thresholds to avoid a threshold event. This, combined with threshold warnings, enabled pharmacies to avoid having their orders blocked and allowed McKesson to evade investigatory and reporting requirements mandated by Vermont law.

145. McKesson even went so far as to [redacted]"[52] Such alerts were sometimes provided by [redacted][53]

146. In 2014, under pressure from renewed DEA and DOJ investigations, McKesson [redacted] To this day, however, [redacted]

[50] MCK-AGMS-041-0066750.
[51] MCK-AGMS-001-0000195.
[52] MCK-AGMS-032-0004671.
[53] MCK-AGMS-032-0004685.

[redacted] despite having made representations [redacted]

[redacted]

5. McKesson manipulated thresholds to support increased opioid sales.

147. When the CSMP was created, requests for threshold changes by pharmacy customers were supposed to be [redacted] However, in the face of ever-increasing prescription opioid sales, and as the opioid crisis ballooned, McKesson actively [redacted].

148. In order for a pharmacy to obtain a threshold increase, the CSMP required submission of a Threshold Change Request ("TCR") form. Threshold increases could be permanent or temporary. The completed TCR form was supposed to include a documented justification for the increase based on information gathered by McKesson sales personnel or Distribution Center Managers, [redacted]

149. However, the DRA responsible for Vermont and the Northeast region has admitted under oath that [redacted].[54] Another McKesson anti-diversion employee testified that [redacted]

[54] Deposition of Michael Oriente, July 19, 2018, MCK-AGMS-032-0003732, at 520-522.

[redacted][55]

150. The conflict of interest between sales and regulatory duties comes as no surprise, because [redacted][56] If McKesson blocked suspicious orders or stopped doing business with a pharmacy, sales employees would [redacted][57]

151. Given this conflict of interest, thresholds were routinely and improperly [redacted] For example, McKesson's DRAs [redacted] In some instances, if a pharmacy called in to request a threshold increase after receiving [redacted]

[55] Deposition of Michael Bishop, January 9, 2019, MCK-AMGS-084-0000001, at 29.
[56] [redacted], MCK-AGMS-032-004738.
[57] Deposition of Michael Oriente, July 19, 2018, MCK-AGMS-032-0003732, at 158-160.

[redacted]

152. Information to justify threshold change requests was often merely collected [redacted]

153. McKesson also increased thresholds without appropriate justification and without adequate investigation. These problems were systemic. For example, from [redacted] through [redacted]

154. Although a particular pharmacy's [redacted] was not in and of itself a sufficient justification to increase thresholds in most cases, in one region [redacted] At one of the pharmacies for which [redacted]

[redacted][58]

155. Mirroring these systemic and nationwide problems, diligence records for pharmacies in Vermont [redacted] in Rutland County, Vermont [redacted][59] [redacted] Orleans County, Vermont [redacted][60]

156. McKesson personnel even took it upon themselves to initiate threshold increases without waiting for pharmacies to make the request—and then failed to file any documentation at all. In one alarming example, [redacted]

157. In another example, [redacted]

[58] [redacted] MCK-AGMS-019-0005802.
[59] MCK-AGMS-066-0000177.
[60] MCK-AGMS-066-0000226.

[redacted][61]

158. Notably, preemptive threshold increases were often granted [redacted]

159. In yet another example, [redacted]. In justifying this broad increase, one McKesson employee suggested that McKesson [redacted]. In response, McKesson employees improperly [redacted]

160. McKesson personnel also improperly [redacted]

161. The result of McKesson's poorly designed threshold change system was evident in Vermont. A sample of pharmacies investigated by the State shows [redacted]

[61] MCK-AGMS-032-0003383 at 12.

162. These practices should have stopped in [redacted]

163. The threshold system, touted as the cornerstone of McKesson's 2008 CSMP, thus, never served its purpose. McKesson did not "set" and then "maintain" thresholds. The thresholds did not meaningfully restrict McKesson's customers from obtaining opioid drugs, but instead were used to accommodate whatever pharmacy customers wanted to purchase, or they were set so high that they never triggered any review.

164. The result was a consistent pattern of excessive opioid sales in Vermont. For example, [redacted], McKesson shipped approximately [redacted] opioid pills to a pharmacy in [redacted] Similarly, McKesson shipped [redacted] opioid pills to another pharmacy in [redacted] In 2011 McKesson shipped approximately [redacted] opioid pills to [redacted]

D. McKesson failed to adhere to the terms of its anti-diversion program.

165. In addition to its failure to design an effective anti-diversion program, McKesson also systemically failed to implement the flawed components of the CSMP in Vermont and

nationwide. McKesson consistently understaffed its anti-diversion department, inhibiting its ability to carry out diligent investigations of its opioid drug pharmacy customers; failed to report or otherwise diligently investigate all orders that exceeded a set threshold; and allowed large chain pharmacies to conduct their own diligence investigations and police themselves with little to no oversight by McKesson.

1. McKesson understaffed and undertrained its anti-diversion department.

166. DRAs were the only [redacted] responsible for [redacted] In one region, a DRA was responsible for [redacted] Given that volume, the DRA [redacted] At this rate, it would take [redacted] years to complete a single visit to each of the pharmacies for which the DRA was responsible. This understaffing occurred despite the fact that McKesson knew or should have known that the [redacted]

167. In addition to this understaffing, neither full-time anti-diversion personnel nor front-line sales employees [redacted] One sales employee [redacted] Similarly, a former McKesson employee stated that even after [redacted] of working in the Regulatory Affairs Department he did not have [redacted]

[redacted][62] did not recall [redacted], did not understand the [redacted], and stated [redacted][63]

168. While McKesson incentivized sales personnel to increase sales, little or no effort was focused on [redacted]

2. McKesson failed to conduct investigations of suspicious orders to detect and prevent diversion.

169. As discussed in Section II.C.1., the CSMP implemented a three-tiered investigatory process that was supposed to identify orders that were suspicious and facilitate reporting to the DEA but consistently failed to do so. In practice, however, McKesson conducted some investigations into orders that exceeded threshold limits, termed Level 1 reviews, in name only and failed to follow even the low bar required by the CSMP. Instead, McKesson often used threshold events as an opportunity to [redacted].

170. Critically, Level 1 Reviews did not [redacted] In the North East region, which included Vermont, [redacted] In other

[62] Deposition of Michael Bishop, January 9, 2019, MCK-AMGS-084-0000001, at 18-20.
[63] Deposition of Michael Bishop, January 9, 2019, MCK-AMGS-084-0000001, at 21; 62; 109.

instances, [redacted]

For example, when a threshold event triggered a Level 1 review for a pharmacy [redacted]

[redacted].[64]

171. McKesson's employees were also left to [redacted] McKesson also failed to standardize the interview questions for pharmacy site visits and interviews. One DRA noted that he created his own [redacted] Despite directing employees to consider various red flags, McKesson had no standard policy or practice for evaluating red flags. And deciding whether to stop supplying a pharmacy with opioid drugs, or to escalate a review to Level 2 or 3, was largely left to the discretion of [redacted]

172. An internal McKesson audit from [redacted] confirmed [redacted] The audit also found [redacted] In

[64] MCK-AGMS-032-0004751.

many cases, [redacted]

173. These were not isolated incidents, but rather part of a systemic and nationwide problem. [redacted][65]

174. In a [redacted][66]

175. A pharmacy in rural [redacted], Vermont, provides yet another example of McKesson's failure to conduct investigations in response to orders that exceeded thresholds. McKesson documents indicate that this pharmacy had a remarkable history of [redacted] While this deluge of threshold events in and of itself should have triggered a careful investigation of the pharmacy's business practices, there is no [redacted] In fact, there are no [redacted]

[65] MCK-AGMS-076-0000319.
[66] MCK-AGMS-035-0001600 at 2.

[redacted]

176. In some instances, the [redacted] In response, McKesson personnel [redacted] For these instances, McKesson's sample regulatory files contain no indication that McKesson [redacted]

177. As a result of its systematic failure to conduct diligent investigations of threshold events, and in violation of its duty, McKesson failed [redacted] Despite all this, McKesson continued [redacted]

3. McKesson failed to report flagged orders and shipped orders without conducting a diligent investigation.

178. McKesson already has admitted that it failed to report all the suspicious orders that it should have to the DEA. For example, in its 2017 settlement agreement with the DEA and DOJ, McKesson acknowledged that suspicious orders did not get flagged in the system and it did not identify and report all the suspicious orders it should have between 2008 and 2014.

179. McKesson also failed to report and block orders in Vermont. During a similar time period, from [redacted] despite profiting from and shipping approximately [redacted] prescription opioid pills into Vermont during that period. For example, [redacted]

[redacted] Franklin County, Vermont [redacted]

180. Three months later, [redacted] Vermont pharmacy [redacted] Vermont [redacted].

181. Such practices were not limited to Vermont—they were a symptom of McKesson's systemic anti-diversion failures. Often McKesson failed to report any suspicious orders until [redacted]. Only after the DEA [redacted]

182. In [redacted]

[redacted] clear red flags for the presence of diversion. Although it had never previously reported a suspicious order from the [redacted] McKesson claimed [redacted] it failed to [redacted]

183. Further demonstrating its systemic problems, McKesson also failed to [redacted] In addition to the exponential threshold increases [redacted] The owner of this pharmacy and dozens of other participants were later convicted on charges related to a drug trafficking conspiracy.

184. McKesson failed to block or report orders that represented significant multiples of the average monthly orders [redacted]

185. Overall, between [redacted] and [redacted] McKesson failed to [redacted] Because of McKesson's poor implementation of its already inadequately-designed CSMP, McKesson failed to identify, report, and prevent shipment of suspicious orders, as required under Vermont law.

4. McKesson applied a different, even looser, set of rules to its chain pharmacy customers.

186. McKesson wholly abdicated its responsibility to investigate threshold events triggered by orders from its large chain pharmacy customers, in violation of its duties under Vermont law. McKesson's pharmacy customers were typically divided into ISM (independent/small/medium size) and larger chains identified as "RNAs" (Retail National Accounts). When an ISM pharmacy exceeded a threshold, [redacted] However, if a Retail National Account pharmacy did the same, McKesson [redacted]

187. McKesson relied on the corporate offices of the Retail National Accounts to conduct their own due diligence, despite a pattern that the pharmacy chains were violating their duties under federal law. For example, McKesson engaged in this conduct for one Retail National Account that was one of the largest chains serviced by McKesson in Vermont and had a significant history of settlements related to alleged violations of the Controlled Substance Act (CSA) settlements. In 2009, this chain agreed to pay $5 million in civil penalties to settle allegations of violations of the CSA, violations alleged to have occurred in several states from New York to California. This chain entered into another settlement in 2017, agreeing to pay

$834,200 to resolve allegations arising from an investigation in Los Angeles, California. And in late 2018, the chain entered into yet another settlement, agreeing to pay a $300,000 penalty for filling prescriptions at Rhode Island pharmacies over the maximum allowed under state law.

188. This chain has a significant foothold in the Vermont retail pharmacy marketplace: at least 51 individual DEA registration numbers associated with its pharmacies in Vermont with more than 145,000 transactions with these pharmacies from 2014-2018 alone. McKesson's abandonment of its duty allowed McKesson to both maintain profitable business relationships with large chain customers and continue shipping massive quantities of prescription opioids into Vermont without interruption.

189. McKesson's uniform policy of special treatment for chain pharmacies was also evident [redacted][67] McKesson also approved permanent bulk threshold change requests to chains without appropriate reasons or documentation. A permanent threshold increase was provided to [redacted][68] In yet another example, McKesson [redacted]

[67] MCK-AGMS-041-0066748.
[68] MCK-AGMS-032-0004722.

III. Cardinal and McKesson Unfairly and Deceptively Promoted Opioids by Spreading Opioid Manufacturers' Misleading Marketing to Pharmacies and Consumers.

190. Cardinal's and McKesson's contributions to the opioid epidemic are not limited to their escalating sales and failure to design and implement policies that effectively prevented diversion. Defendants' internal documents confirm that they actively marketed prescription opioids to prescribers and pharmacists. Through these marketing activities, they built upon, reinforced, and profited from the drug manufacturers' campaign to deceive healthcare providers about the risks and benefits of prescription opioid use—a campaign that encouraged and normalized over-prescribing and over-dispensing of prescription opioids.

191. Cardinal's and McKesson's promotion and marketing of prescription opioids constitutes an unfair business practice, in the context of their legal duties as licensed distributors of controlled substances and their failure to implement adequate systems to detect, prevent, and report diversion. Their marketing of prescription opioids ranged from [redacted]—to [redacted], disseminated through marketing channels over which they had unique control, as well as promotion and/or administration of prescription savings card programs designed to encourage initiation and long-term use of branded prescription opioids. Through these marketing activities, Cardinal and McKesson built upon and reinforced the opioid manufacturers' deceptive, misleading, and highly successful marketing campaign to promote prescription opioid use.

192. Cardinal's and McKesson's roles in marketing prescription opioids were at odds with their core responsibilities as licensed distributors of controlled substances. These marketing efforts were intended to increase opioid sales, which would thereby increase the supply of

opioids in the community and increase abuse and diversion, further undermining Defendants' already insufficient diversion prevention systems.

193. Cardinal and McKesson profited in two ways from their marketing activities: (1) they were paid by the drug manufacturers to promote their prescription opioids, and/or (2) they were paid from increases in pharmacy drug sales that resulted from these marketing efforts.

194. Defendants focused their marketing efforts on pharmacists because they knew—as did the opioid manufacturers—that pharmacists, as the last healthcare professionals to see patients before medication is dispensed, occupy a unique position of influence over both prescribers and consumers. Particularly over the last few decades, the typical pharmacist's role has evolved from rote dispensing of prescriptions to actively advising on drug therapies.[69]

195. In a 2010 survey by the National Community Pharmacists Association ("NCPA"), pharmacists reported interacting with other health care professionals regarding patients' drug therapy an average of 7.1 times per day. Eighty-one percent of the surveyed pharmacists reported recommending changes to patients' drug regimens, with physicians accepting 73% of those recommendations. Nearly all (93%) of the surveyed pharmacists reported, for example, recommending changes from branded to generic drugs, with physicians accepting 80% of those recommendations.[70]

196. Cardinal expressly acknowledged [redacted]. One Cardinal marketing proposal emphasized to an opioid manufacturer client that [redacted]

[69] https://www.pharmacytimes.com/publications/issue/2015/october2015/the-pharmacists-expanded-role
[70] https://www.pharmacytimes.com/publications/issue/2012/january2012/strong-pharmacy-entrepreneurs-make-for-a-strong-profession

[redacted] Cardinal's proposal advised the drug company that "[redacted][71]

197. Opioid manufacturers that used Defendants' marketing services also knew that pharmacists are key to ensuring that prescriptions are converted to sales. Purdue, for example, asserted in a [redacted][72] In 2015, when Purdue launched its extended-release hydrocodone product, Hysingla, it [redacted][73] Purdue also noted that [redacted][74]

198. Purdue and other manufacturers worked hand-in-glove with Defendants to promote their products—through the distributors—to pharmacies and pharmacists. For example, [redacted]

199. The targeting of pharmacists by Cardinal and McKesson in their marketing activities was particularly problematic because of Cardinal's and McKesson's existing and often long-term business relationships with pharmacies—with whom Defendants shared a legal responsibility to prevent diversion. Opioid distributors, like Defendants, were in a unique and trusted position in the controlled substances supply chain from which they could have spoken

[71] CAH_MDL2804_02879120.
[72] PWG00062629.
[73] PWG000362181.
[74] PWG000362181.

truthfully to their pharmacy customers about the serious risks posed by opioids (including the risk of diversion). They could have remained silent about the benefits and risks of opioids, and simply filled orders and shipped drugs. Instead, Cardinal and McKesson abused their unique position for profit, by contributing to the chorus of deception surrounding opioids.

200. To engage in the promotion of controlled substances at all, under the circumstances detailed in this Complaint, was a dereliction of Defendants' duties to prevent opioid diversion. Through these marketing activities, Defendants contributed to and reinforced the deceptive and misleading marketing messages that healthcare providers received about opioids through other channels. Moreover, much of the Defendants' marketing content was deceptive, because it either affirmatively misrepresented the benefits and risks of prescription opioids, or it omitted important information about the risks of prescription opioids. Both Cardinal and McKesson knew or should have known that these marketing messages—particularly those that misrepresented or omitted material information about the potential for diversion or risks of addiction associated with prescription opioids—were deceptive. Through their unfair and deceptive conduct, Defendants put Vermont consumers at increased risk of harm from the escalating and largely unchecked distribution and sale of prescription opioids, increased availability and diversion of opioids to non-medical use in Vermont, and increased misuse and addiction that has created an epidemic of health problems, overdose, and death in Vermont.

A. Cardinal unfairly and deceptively marketed opioids.

201. Cardinal has actively sought to increase the sale of opioids in Vermont by marketing these dangerous and addictive drugs to pharmacists and prescribers, and even directly to consumers, contrary to its public claim that it merely serves as a secure delivery service for transporting medications from warehouse to pharmacy. Cardinal not only offers marketing

services to its drug manufacturer clients, it incentivizes and encourages manufacturers to use these marketing channels as a way of building their business and increasing sales of prescription opioids.

202. Increased drug sales benefit Cardinal. [redacted]

203. Through Cardinal's marketing programs, it disseminated the drug manufacturers' promotional messages about opioids nationally and, upon information and belief, into Vermont. These marketing activities constituted an unfair business practice, under the circumstances detailed in this Complaint.

204. Cardinal offers a range of marketing services to its drug manufacturer clients. [redacted] For many manufacturers, the cost of Cardinal's marketing services is [redacted][75] [redacted]

[75] CAH_MDL2804_002893641.

[redacted]

205. [redacted]

[redacted]

206. [redacted]

[redacted] A year later, Purdue and three of its current and former executives pled guilty to federal criminal charges connected to their misleading marketing of OxyContin, paying $600 million in fines and other payments. [redacted]

207. As another example, [redacted]

[redacted] By late 2013, INSYS had publicly announced that it was under federal investigation and had received a subpoena from the U.S. Department of Health and Human Services inquiring into INSYS's sales and marketing practices relating to SUBSYS. [redacted]

208. From at least 2010 to 2017, Cardinal's marketing team routinely [redacted]

209. Cardinal did not simply [redacted], it also [redacted]

210. Cardinal's marketing programs were not [redacted]

1. Cardinal engaged in an unfair business practice by marketing prescription opioids through a variety of marketing programs.

211. Cardinal worked to increase sales of opioids through a range of in-house marketing platforms directed at prescribers, pharmacists, and consumers, implemented nationally

and, on information and belief, in Vermont. These marketing activities constituted an unfair business practice, under the circumstances detailed in this Complaint.

212. ***Direct-to-Consumer Marketing.*** Cardinal markets drugs directly to consumers through [redacted] Cardinal describes this program, [redacted][76]

213. There is ample evidence that this type of marketing is effective. A 2014 audience-research study conducted by Nielsen found 74% of PHN viewers indicated advertisements are more believable when viewed in a pharmacy; 49% of viewers surveyed indicated that they felt encouraged to discuss a product or brand they had seen on the network with their pharmacist; 48% indicated that after seeing advertisements on PHN, they felt motivated to discuss those products or brands with their physicians; and 13% of consumers who have seen advertisements on PHN have purchased those products or brands.[77]

214. As John Disher, Cardinal's Senior Manager for Marketing and Business Development, said in 2014: "This study again confirms that consumers consider advertising messages on Pharmacy Health Network to be informative and highly credible, and that ads on our network drive action, by encouraging consumers to talk with their pharmacists and physicians about products they see on our network … As our network continues to receive a

[76] CAH_MULTISTATE_0013372.
[77] *Nielson Study Confirms Ads on Cardinal Health's Retail Pharmacy Digital Advertising Network Motivate Consumers to Discuss, Purchase Products* (March 17, 2014), https://digitalsignagefederation.wildapricot.org/widget/memberpress/1520048.

positive response from advertisers and consumers alike, we look forward to expanding the number of stores and advertisers that participate in the program.[78]

215. In fact, additional studies show that, as of November 2015, Cardinal's PHN was proven to increase sales of advertised products.[79]

216. Although it is currently unknown to the State whether opioid advertisements were run [redacted][80] [redacted][81]

217. ***Direct Mail Marketing.*** Cardinal utilizes [redacted]

218. Cardinal charges [redacted]

219. ***Email Marketing.*** Cardinal also [redacted]

[78] *Id.* (emphasis added).
[79] Respario, *Case Study: Cardinal Health Engages Retail Pharmacy Customers Through Digital Signage Network* (November 2015), http://respario.com/wp-content/uploads/2015/11/respario-case-study-cardinalhealth.pdf.
[80] CAH_MDL2804_01296417.
[81] CAH_MDL2804_00134274.

220. [redacted]

221. Cardinal claims that through [redacted] Cardinal specifically promotes its ability to [redacted] In its own words, Cardinal advertises that its "commercial team helps to position [a manufacturer's] product for success by identifying physicians who treat unique patient populations, understanding prescriber behavior and driving engagement."

222. From 2010 through at least 2015, Cardinal used [redacted] [82]

223. From at least 2012 through 2017, Cardinal frequently used [redacted] [83]

[redacted]

224. ***Marketing in Customer Newsletters.*** Cardinal also offers opioid marketing through [redacted]

225. [redacted]

226. Drug manufacturers can purchase [redacted]

227. Cardinal used [redacted] including pharmacists in Vermont, from at least 2009 through 2017.[84]

228. ***Telemarketing.*** Cardinal offers its manufacturer clients the option of purchasing [redacted]

[redacted]

[84] [redacted]

229. One telemarketing script [redacted][86]

230. ***Advertisements on Ordering Platform.*** Cardinal also runs drug advertisements on [redacted]

231. Cardinal offers drug manufacturers the options of [redacted]

[85] Controlled substances—including opioids—are divided into Schedules, depending on their potential for abuse. Schedule III drugs have a potential for abuse that is lower than drugs in Schedules I and II, and abuse of these drugs may lead to moderate or low physical dependence or high psychological dependence.

[86] [redacted]

[redacted]

232. [redacted][87] [redacted]

[redacted][88]

233. ***Pharmacy Rebates.*** Cardinal further encourages purchases of opioids through its [redacted]

234. [redacted]

[redacted][89]

[87] CAH_MDL2804_00134788.

[88] [redacted]

[89] [redacted]

235. ***Auto-Shipments.*** Through its "[redacted]" program, Cardinal [redacted]

236. [redacted]

2. Cardinal deceptively marketed opioids.

237. In addition to being an unfair business practice, some of Cardinal's marketing content was also deceptive. These marketing messages—like other opioid marketing messages disseminated in the medical community by opioid manufacturers—contained deceptive statements about the benefits of particular opioids or misleading omissions about the serious risks associated with them.

238. Cardinal's deceptive and misleading marketing of opioids contributed to—and built upon—the deceptions that drug manufacturers were disseminating through other channels.

239. Cardinal disseminated certain opioid advertisements that contained deceptive statements regarding the risk of addiction, abuse, and diversion posed by these drugs. For example, [redacted][91] This

[redacted]

[90] Schedule II controlled substances are so-categorized because they have a high potential for abuse, which may lead to severe psychological and physical dependence.
[91] CAH_MDL2804_02957392.

advertisement was sent to [redacted][92]

240. Moreover, many of Cardinal's opioid advertisements failed to disclose the serious risks associated with opioids or to provide "fair balance" in their representation of the risks and benefits of the drugs. For example, [redacted][93] [redacted] Likewise, Cardinal disseminated advertisements promoting opioids without mentioning any of the drugs' risks—providing, at most, [redacted] These advertisements failed to provide "fair balance" and had material omissions, which rendered them misleading to their intended recipients, in violation of the Consumer Protection Act.

241. Cardinal disseminated advertisements that were not clearly labeled as paid advertising content and would reasonably have been mistaken by Cardinal's pharmacy customers as neutral informational content provided by Cardinal.

[92] CAH_MDL2804_02955823.
[93] CAH_MDL2804_02955979.

242. Through these and other advertisements, Cardinal took advantage of its unique position of trust as a distributor of controlled substances to promote opioids in deceptive and misleading ways. Cardinal knew or should have known that these advertisements—particularly those that misrepresented the risk of diversion for, or addictive potential of, prescription opioids—were deceptive, because of its own heightened duties, as a distributor, when handling controlled substances. Moreover, when engaging in pharmaceutical marketing, Cardinal knew or should have known about the attendant legal obligations, including the obligation to provide "fair balance" and adequately disclose the risks associated with the drugs it was promoting.

B. McKesson unfairly and deceptively marketed opioids nationally and in Vermont.

243. McKesson actively sought to increase the sale of opioids by assisting manufacturers in marketing these dangerous, addictive, and misuse- and abuse-prone drugs.

1. McKesson engaged in an unfair business practice by marketing prescription opioids.

244. McKesson's marketing programs disseminated drug manufacturers' promotional messages about opioids nationally and, upon information and belief, into Vermont. These marketing activities constituted an unfair business practice, under the circumstances detailed in this Complaint.

245. McKesson claims to have had a policy of not [redacted] Despite that policy, [redacted], McKesson's marketing team identified [redacted]

246. [redacted]

[redacted][94]

247. ***Auto-Shipments.*** Specifically, McKesson promoted prescription opioids through its [redacted] program. This marketing program identified [redacted]

248. McKesson described [redacted]

(emphasis in the original).[95]

249. The prescription opioids McKesson promoted and auto-shipped (including to Vermont pharmacies) through [redacted] include the following:

Opioid	Manufacturer	Approximate Date[96]
[redacted]	[redacted]	[redacted]

250. McKesson charged manufacturers $[redacted] program. McKesson eventually [redacted]

[94] MCKAGMS-069-0000020.
[95] MCK-AGMS-019-0008109, -8171; MCK-AGMS-038-0000040.
[96] All dates in this table reflect implementation dates.

[redacted][97] [redacted], McKesson lamented that it would [redacted] and would need to [redacted][98]

251. ***Email Marketing.*** McKesson also promoted opioids through the [redacted] program, which sent [redacted] McKesson described [redacted] McKesson promoted [redacted][99]

252. The prescription opioids that McKesson marketed through [redacted] include the following:

Opioid	Manufacturer	Approximate Date[100]
[redacted]	[redacted]	[redacted]

253. McKesson charged manufacturers between $[redacted] $[redacted] [redacted]

254. ***Fax Marketing.*** McKesson promoted opioids through its [redacted] program, which sent [redacted] McKesson described [redacted] as having the ability to distribute [redacted]

255. The prescription opioids that McKesson promoted through [redacted] include the following:

[97] MCK-AGMS-069-0002800.
[98] MCK-AGMS-069-0002796.
[99] MCK-AGMS-019-0008143; MCK-AGMS-019-0008201.
[100] The dates in this table reflect the implementation date or, if unavailable, the date the marketing agreement was executed.

Opioid	Manufacturer	Approximate Date[101]
[redacted]	[redacted]	[redacted]

256. McKesson charged manufacturers between $[redacted] $[redacted] campaign.

257. ***Advertisements on Ordering Platform.*** McKesson [redacted] McKesson touted [redacted] McKesson boasted that more than [redacted] of its pharmacy customers accessed [redacted] and [redacted] of its independent pharmacy customers accessed the portal [redacted]

258. The prescription opioids that McKesson promoted through [redacted] include the following:

Opioid	Manufacturer	Approximate Date[102]
[redacted]	[redacted]	[redacted]

259. McKesson charged between $[redacted] $[redacted] per [redacted] on [redacted].

260. ***Direct Mail Marketing.*** Lastly, McKesson used its [redacted] program to promote opioids [redacted] McKesson promoted [redacted]

[101] All dates in this table reflect implementation dates.
[102] The dates in this table reflect the implementation date or, if unavailable, the date the marketing agreement was executed.

[redacted]

261. McKesson used the [redacted] program to promote opioids. For example, in January 2012, McKesson [redacted] nationally. According to the agreement between McKesson and [redacted], the estimated cost for [redacted].

262. [redacted] Calling it a [redacted] McKesson offered its [redacted] to provide a way for pharmacists to [redacted][103] [redacted] [redacted][104]

263. Through the program, [redacted]

264. As part of the program, [redacted][105] [redacted] [redacted][106]

[103] MCK-AGMS-069-0003449.
[104] MCK-AGMS-069-0000108.
[105] MCK-AGMS-028-0080256.
[106] MCK-AGMS-028-0083903.

265. McKesson touted the [redacted] as a proven way to [redacted] [107]

266. [redacted] [108]

2. McKesson deceptively marketed opioids.

267. In addition to being an unfair business practice, some of McKesson's marketing content was also deceptive. The opioid advertisements that McKesson disseminated were deceptive and misleading because they failed to disclose the serious risks of addiction, abuse, and diversion associated with opioids. The advertisements failed to provide fair balance of the risks and benefits of opioid use.

268. McKesson's deceptive and misleading marketing of opioids contributed to—and built upon—the deceptions that drug manufacturers were disseminating through other channels.

269. For example, McKesson distributed a [redacted] advertisement to [redacted] The advertisement emphasized that [redacted]

[107] MCK-AGMS-028-0073543.
[108] PVT0001185.

[redacted] (emphasis in original).[109] Yet nowhere does the advertisement mention the risk for addiction and dependence from the opioid ingredient in the drug.

270. McKesson disseminated other advertisements [redacted]

271. Finally, in [redacted] Purdue's now-defunct website, TeamAgainstOpioidAbuse.com. [redacted] a Purdue website that is known to have spread misleading information regarding the effectiveness of abuse-deterrent properties of certain opioid formulations.

272. Through these and other advertisements, McKesson took advantage of its unique position of trust, as a distributor of controlled substances, to promote opioids in deceptive ways. McKesson knew or should have known that these advertisements—particularly those that misrepresented the risk of diversion for, or addictive potential of, prescription opioids—were deceptive, because of its own heightened duties, as a distributor, when handling controlled substances. Moreover, when engaging in pharmaceutical marketing, McKesson knew or should have known about the attendant legal obligations, including the obligation to provide "fair balance" and adequately disclose the risks associated with the drugs it was promoting.

C. Cardinal and McKesson helped to initiate and facilitate long-term opioid use by disseminating prescription savings cards for these drugs.

273. Cardinal and McKesson also engaged in an unfair business practice by promoting—and in McKesson's case, administering—prescription savings card programs, which encouraged and supported both initiation and long-term use of prescription opioids.

[109] MCK-AGMS-038-0000008; *see also* MCK-AMGS-038-0000006, -7.

274. Opioid manufacturers drive initiation and long-term use of their drugs through the distribution of promotional prescription "savings cards" (a/k/a prescription "discount cards") to consumers. Savings cards reduce or eliminate the out-of-pocket cost of these drugs, thus reducing or eliminating any financial obstacles to initiating or continuing long-term treatment with expensive, brand-name drugs—including brand-name opioids.

275. Cardinal promoted and disseminated savings cards through [redacted] for opioids [redacted]:

Opioid	Manufacturer	Savings Card Offer	Approx. Year
[redacted]	[redacted]	[redacted]	[redacted]

276. McKesson administers [redacted] McKesson runs [redacted] A patient may redeem the discount at the point of sale (i.e., a pharmacy) and receive the manufacturer's pre-determined discount off the purchase price of the medication. The

pharmacy submits claims to McKesson for the difference; McKesson reimburses the pharmacy; and then McKesson submits those claims to the drug manufacturer for reimbursement.

277. An affiliate of McKesson, [redacted], also administers a similar program, [redacted], eliminating the need for patients and pharmacists to submit claims to or through McKesson for reimbursement.

278. In promoting its [redacted][110]

279. The opioids that McKesson promoted through savings-card programs include the following:

Opioid	Manufacturer	Savings Card Offer	Approx. Year
[redacted]	[redacted]	[redacted]	[redacted]

280. The savings cards that Defendants promoted and disseminated were intended to—and did—encourage patients to initiate and stay on long-term opioid therapy by making it easier

[110] MCK-AGMS-069-0000091 to -107.

and cheaper to access prescription opioids, even though there are **no studies demonstrating the safety or efficacy of long-term opioid use beyond 12 weeks**. In other words, Defendants' savings cards facilitated long-term use of the drugs, well beyond the duration of treatment for which there was scientific support.

IV. The Foreseeable Consequences of Defendants' Conduct Include Increased Opioid Misuse, Addiction, Diversion, Overdose, and Death in Vermont Communities.

281. Vermont—like many other states—saw an explosion in opioid prescribing between 1996 and 2008 that has fueled an escalating public health crisis of opioid overuse, misuse, and abuse over the last decade. The effects of this crisis are reverberating through Vermont to this day and are expected to continue for decades. One recently-published analysis concluded that, under the status quo, the number of opioid overdose deaths nationwide is projected to increase from 33,100 per year in 2015 to 81,700 deaths per year by 2025.[111]

282. Despite increased public awareness surrounding the dangers of opioid use and Vermont's own extensive and nationally recognized efforts to reduce overprescribing and to prevent and treat opioid abuse and addiction, opioid sales only began to meaningfully decline in the State very recently, after nearly two decades of unacceptably and unnecessarily high prescribing levels. In 2010, for example, 482,572 opioid prescriptions were dispensed in Vermont, a state with a population of just over 625,000.[112] In 2015, the number of opioid

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[111] Chen, Qiushi, *et al., Prevention of Prescription Opioid Misuse and Projected Overdose Deaths in the United States*, JAMA Network Open, Feb. 1, 2019.

[112] Anne VanDonsel, Shayla Livingston, and John Searles (Vermont Department of Health), *Opioids in Vermont: Prevalence, Risk, and Impact* (October 27, 2016), http://www healthvermont.gov/sites/default/files/documents/2016/12/ADAP_Opioids_Prevalence_Risk_Impact.pdf, at 30 ("Number of Prescriptions by Drug Type and Year"); Vermont Department of Health, *Special Report: Opioid Prescriptions and Benzodiazepines, 2014* (February 2016), http://www healthvermont.gov/sites/default/files/documents/2016/12/ADAP_Opioids_Benzodiazepenes_Report.pdf, at 3.

prescriptions increased to 498,973[113]—the equivalent of giving a prescription to every 1.3 people living in Vermont, including infants.

283. These high levels of prescription opioid sales reflect more than legitimate medical use. Increased sales and availability of these drugs in Vermont communities have been accompanied by increased abuse and diversion, leading many Vermonters to misuse opioids, to become addicted to them, and to escalate to the use of heroin and fentanyl. These patterns have led to overdoses and premature death.

284. Increased rates of prescription opioid diversion—and the serious public health consequences—were foreseeable consequences of the Defendants' promotion of these opioids and their failure to implement effective systems to detect and prevent diversion of these dangerous drugs.

A. Prescription opioid diversion is widespread in Vermont.

285. Prescription opioids are diverted away from legitimate medical channels in several ways. Some prescription drugs are stolen from warehouses and pharmacies. Some are prescribed to persons posing as medical patients, who then sell the pills to illegal dealers. But the vast majority of people who misuse prescription opioids obtain their drugs (1) from friends or family members, or (2) through their own prescriptions. This means that, for most people who misuse opioids, the source of their drugs can typically be found in the excess supply of drugs in the community, beyond what is needed for legitimate medical purposes.

286. More than twenty years ago, when the prescription and sale of opioids were limited to a narrow set of patients who suffered from severe medical conditions and had close oversight from treating physicians—who had been educated to understand that opioids were dangerous and addictive, and should be prescribed in relatively narrow circumstances—there

[113] *Id.*

was little or no excess supply of prescription opioids in communities available for misuse. But when Purdue Pharma introduced its extended-release oxycodone formulation branded as OxyContin ER in 1996, the company launched a massive marketing campaign that changed the landscape of opioid prescribing and over-use for decades to follow. Prescription opioid diversion became a serious problem as over-prescribing rose for less serious conditions—both acute and chronic—and physician oversight and vigilance decreased. This change in culture was driven by aggressive marketing of these drugs—not only by the manufacturers, but also, as it turns out, by distributors like Cardinal and McKesson. As a result of this marketing, and the resulting shift in the medical consensus around opioid prescribing, it became common for healthcare providers to prescribe opioids for long-term conditions like chronic lower-back pain, minor injuries like sprains, and post-surgical pain from minor procedures, like removal of wisdom teeth. The supply of opioids available in communities across Vermont and the United States ballooned.

287. By 2002 to 2003, more than 5% of Vermonters had **misused** prescription pain relievers in the preceding twelve months. Opioid misuse was particularly prevalent among young people: in 2005 to 2006, for example, an estimated 7% of teens (ages 12-17) and 15% of young adults (ages 18-25) had misused prescription pain relievers in the preceding year.

288. These numbers remained consistently high for nearly a decade. In 2010 and 2011, it was still the case that more than 5% of all Vermonters—roughly 30,000 people—had misused prescription opioids within the prior twelve months.

289. Since then, through increased awareness, regulatory efforts, and addiction treatment, the rate of prescription opioid misuse in Vermont has begun to decrease—but not by enough. Many Vermonters still struggle with prescription opioid abuse and addiction, and many have escalated to abuse of heroin and other illicit opiates.

B. Defendants knew or should have known that inappropriately high levels of opioid sales would lead to increased diversion and harm to public health.

290. Because of their place in the closed system of prescription drug distribution and their significant market share, Cardinal and McKesson were in a unique position to see that an epidemic of prescription opioid overprescribing and diversion was unfolding.

291. Defendants tracked news coverage of the opioid epidemic as early as [redacted] [114] [redacted] [115]

292. [redacted], discussing an FDA proposal intended to reduce the misuse and abuse of long-acting painkillers like OxyContin. [redacted]

[114] Deposition of Nicholas B. Rausch, Nov. 16, 2018, CAH_MULTISTATE_0017218, at 28:10-15.
[115] Deposition of Mark Hartman, Nov. 15, 2018, CAH_MULTISTATE_0016766, at 320:21-322:8.

293. Cardinal personnel continued [redacted][116]

294. [redacted][117]

295. Cardinal also knew about the devastating effects that the opioid crisis was having in Vermont in particular. [redacted]

296. [redacted]

[116] CAH_MDL2804_01103324

[117] CAH_MDL2804_03171557-03171563 [redacted] CAH_MDL2804_03179982 (article stating: [redacted]

[redacted]

297. Cardinal also tracked and circulated articles internally about the abuse and diversion of specific drugs. [redacted]

298. Both Defendants were aware of Vermont's efforts to restrict prescribing of certain high-risk drugs. For example, in 2014, Vermont put prescribing restrictions in place for Zohydro ER, a hydrocodone drug, only permitting physicians to prescribe Zohydro if they could document that other avenues for treatment had been ineffective for the patient. [redacted] McKesson—which was also a member of HDA, and would presumably have received the same information—continued to promote [redacted]

299. As for McKesson, the company knew of the opioid epidemic as early as 2001. The company admitted [redacted]

300. Later, in August 2013, McKesson [redacted][118][redacted]

301. Defendants also utilized sophisticated data visualization and analysis to track exactly how many opioids were being prescribed and sold in every geographic area they serviced, thereby making Defendants aware of the scope of the opioid epidemic and the flow of opioids into communities, including in Vermont. During this same time, the DEA repeatedly told Defendants that their internal controls were insufficient to detect, report, and prevent increasing opioid diversion. *See infra* Section V.A–B.

302. Specifically, Defendants had access to data from IQVIA (previously IMS Health Incorporated and Quintiles) and Symphony Health, which provide data analytics to the healthcare industry.[119] IQVIA has a databank of over "520 million non-identified patient records" and prescription drug data "to state, county, zip code or prescriber granularity."[120] In addition, IQVIA provides services that allow corporations such as Defendants to determine where individual products are sold,[121] "granular prescription performance," and "weekly

[118] MCK-AGMS-069-0001025.
[119] https://www.iqvia.com/about-us; https://symphonyhealth.prahs.com/about/
[120] https://www.iqvia.com/institute/research-support
[121] https://www.iqvia.com/locations/united-states/commercial-operations/essential-information/sales-information

prescription dispensing" through various proprietary databases, such as DDD, Xponent, and National Prescription Audit.[122]

303. Symphony Health offers similarly extensive information, with databases including medical, hospital, and prescription claims data along with "point-of-sale prescription data, non-retail invoice data, and demographic data."[123]

304. McKesson used [redacted] In fact, [redacted]

305. [redacted][125]

[122] https://www.iqvia.com/locations/united-states/commercial-operations/essential-information/sales-information
[123] https://symphonyhealth.prahs.com/product/idv/
[124] MCK-AGMS-028-0128169; *see also* MCK-AGMS-028-0045067.
[125] MCK-AGMS-028-0128171, -177.

306. Symphony is cited as a [redacted] In addition, [redacted] Symphony Health provided [redacted]

307. In addition, [redacted]

308. Cardinal likewise [redacted]

309. Defendants tracked the flow of opioids closely, and understood the connection between increasing opioid sales and diversion. Yet Defendants designed their own diversion control systems to allow the shipment of prescription opioids in quantities that vastly exceeded any plausible medical need in the communities they served without triggering red flags or regulatory reporting. Defendants set excessively high thresholds and then relied on these flawed

thresholds as the primary indicator of potential diversion. As detailed in Section II *supra*, they made no attempt to set these thresholds at levels consistent with legitimate medical use of opioids. Instead, initial thresholds were tied to [redacted], which at the time set records for opioid overprescribing. And even then, Defendants routinely permitted, and in fact encouraged, prescription opioid sales that surpassed their excessive thresholds. *See supra* Section II.

310. Defendants knew or should have known that diffuse channels of prescription opioid diversion—including sharing of the drugs with friends and family members—were the most common.

311. Defendants knew or should have known that continuing to promote and market opioids to prescribers, pharmacists, and directly to consumers would lead to increased supply of opioids in Vermont communities and to increased diversion. Cardinal and McKesson were sophisticated purveyors of opioid marketing—they knew how effective Purdue and other manufacturers had been in expanding the use of prescription opioids, and they built opioid marketing services into their distribution contracts with the manufacturers. Overprescribing, driven by reckless and deceptive marketing tactics, was already a well-documented and pervasive problem.

312. Defendants also knew that the marketing of controlled substances in general—and opioids in particular—was a problematic practice. Both Cardinal and McKesson implemented marketing policies and internal guidelines [redacted] of controlled substances. Cardinal's regulatory compliance personnel even understood—[redacted]

However, despite the risks associated with this marketing—which both Defendants appear to have known and understood—they continued to market opioids.

313. Defendants also knew or should have known that their diversion control systems did not work: their anti-diversion and suspicious order monitoring programs were designed with loopholes to minimize the detection of suspicious orders. Defendants actively helped their pharmacy customers to subvert the systems' protections against diversion, and the protections that did exist were deliberately flawed from the start. It is no surprise that Defendants' anti-diversion systems did not prevent the diversion of prescription opioids, as explained in Section II *supra*.

314. As licensed distributors of controlled substances and giants in the prescription drug distribution industry, Defendants knew or should have known the risks of the controlled substances that they sold and failed to control. Prescription opioids present such serious health risks to consumers, and are so prone to diversion, that the federal government requires drug distributors (like Cardinal and McKesson) to store them in a locked vault with walls, floors, and ceilings made of "at least 8 inches of reinforced concrete;"[126] to transport them with extensive security precautions;[127] and to sell them only to DEA-registered pharmacies whose orders distributors must carefully monitor and investigate (and report to DEA, if suspicious).[128] Defendants knew and accepted the rules when they entered the marketplace to sell these dangerous controlled substances.

315. The resulting harm—to both Vermont consumers and to the State—was foreseeable to the Defendants and could have been prevented. Defendants instead prioritized profit above their legal responsibilities and the well-being of the public, with devastating results.

[126] 21 C.F.R. § 1301.72(a)(2)(3)(i).
[127] *See, e.g.*, 21 C.F.R. §§ 1301.74(e) & 1301.77.
[128] *See supra* Part I.

C. Vermont has suffered the devastating effects of widespread prescription opioid diversion.

316. Widespread prescription opioid diversion—and the resulting epidemic of addiction—have caused devastating consequences for Vermont and its citizens.

317. This high volume of opioid use and diversion leads to increased incidence of dependence and addiction—a significant public health problem in Vermont. In a 2014 survey by the U.S. Department of Health and Human Services, more than three percent of Vermonters—approximately 18,000 people—reported a dependence on a controlled substance.[129] Vermont ranks as the 8th-highest state for drug dependence nationwide,[130] despite other favorable health indicators like better access to health care and insurance coverage as compared to other states. [131]

318. Opioids have been killing Vermont citizens at skyrocketing rates, and a common origin is prescription opioids. Drug-related fatalities involving opioids nearly tripled between 2010 and 2018.[132] While the national average of opioid-related overdose deaths in 2016 was 13.3 per 100,000 persons, the rate in Vermont was 18.4, 38% higher than the national average.[133] And these overdose deaths have a broad impact—in a state like Vermont, there are no anonymous deaths.

319. The link between prescription opioids and "street drugs" like heroin and fentanyl fuels the opioid crisis. Many addicts begin with a legal opioid prescription from their doctor or

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[129] amfAR Opioid & Health Indicators Database, *Percent of people 12+ Reporting Drug Dependence*, http://opioid.amfar.org/indicator/drugdep.
[130] *Id.*
[131] *See State Health Assessment Plan - Healthy Vermonters 2020* (December 2012), http://www healthvermont.gov/sites/default/files/documents/2016/11/Healthy%20Vermonters%202020%20Report.pdf, at 13, 5, 27.
[132] Vermont Department of Health, *Opioid-Related Fatalities Among Vermonters* (updated February 2019), http://www healthvermont.gov/sites/default/files/documents/pdf/ADAP_Data_Brief_Opioid_Related_Fatalities.pdf.
[133] National Institute on Drug Abuse, *Vermont Opioid Summary* (March 2018), https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/vermont-opioid-summary.

by taking a pill from a prescription bottle belonging to a family member or friend.[134] Prescription opioid users also are far likelier to use illegal opioids like heroin and fentanyl. U.S. Centers for Disease Control and Prevention ("CDC") statistics show that people addicted to prescription opioids are **40 times more likely** also to be addicted to heroin. The same CDC report shows that **nearly half** (45%) of people who used heroin also were addicted to prescription opioid painkillers.[135] In 2017, the Vermont Department of Health reported that 80% of new heroin users also had a history of misusing prescription opioids.[136]

320. The heroin/fentanyl problem in Vermont is acute—in 2018, fentanyl was involved in three-fourths of all opiate-related fatalities, and heroin was involved in over half of all opiate-related fatalities.[137] The number of fatal overdoses involving fentanyl in particular has skyrocketed in recent years—a **twentyfold increase** from 4 fatalities in 2010 to 83 fatalities in 2018.[138]

321. Beyond just addiction, there are additional and serious health dangers associated with illicit heroin and fentanyl use, including collapsed veins, bacterial infections of the blood and heart, lung complications, and depression. When heroin is administered by injection, the sharing of needles or bodily fluids puts users at heightened risk for HIV and Hepatitis B and C—serious diseases that can be transmitted to sexual partners and children.[139] The concern about rising rates of HIV and Hepatitis C is very real in Vermont: in 2016, the CDC identified **two**

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[134] Nora Volkow and Francis Collins, National Institute on Drug Abuse, "*All Scientific Hands On Deck*" *to End the Opioid Crisis*, May 31, 2017, https://www.drugabuse.gov/about-nida/noras-blog/2017/05/all-scientific-hands-deck-to-end-opioid-crisis ("While there were nearly 20,000 overdoses in 2015 due to heroin or fentanyl, the trajectory of opioid addiction usually begins with prescription opioid misuse. Some people with opioid addiction began by taking diverted pills from friends and family members, but others began with an opioid prescription of their own").
[135] Centers for Disease Control and Prevention, *Today's Heroin Epidemic*, https://www.cdc.gov/vitalsigns/heroin/.
[136] Vermont Department of Health, *Opioid Misuse, Abuse & Dependence in Vermont Data Brief*, April 2017, http://www healthvermont.gov/sites/default/files/documents/pdf/ADAP_data_brief_opiodmisuse.pdf.
[137] *Opioid-Related Fatalities Among Vermonters, supra* n.133, at 1.
[138] *Id.* at 2.
[139] National Institute on Drug Abuse, *What are the medical complications of chronic heroin use?* (June, 2018) at 11, https://www.drugabuse.gov/publications/research-reports/heroin/what-are-medical-complications-chronic-heroin-use.

Vermont counties—Essex and Windham—out of the more than 3,100 counties across the entire United States as among those **in the 95th percentile (top 5% nationwide) at greatest risk** for outbreaks of HIV and Hepatitis C.[140]

322. While heroin and fentanyl have contributed to the increasing number of opioid deaths in Vermont, the majority of opioid fatalities are causally linked to opioid prescriptions—which many heroin and fentanyl abusers have in their system at the time of their fatal overdose or have used at some point prior to their fatal overdose. A study by the Vermont Prescription Monitoring System found that 85% of opioid-related accidental fatalities in Vermont had received an opioid prescription within the last five years[141] and that 25% percent had received an opioid prescription within 30 days prior to their death.[142]

323. In Vermont, 90.6% of opioid-related fatalities in 2015 occurred in people who had controlled substance prescription histories. Of the decedents who had been given an opioid prescription during the year prior to their death, the average opioid prescription supply was 261 days.[143]

324. In the most recent years for which data from the Vermont Department of Health is available (2015, 2016, 2017, and 2018), prescription opioids have been involved in roughly one-third of opioid-related deaths in Vermont.[144]

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[140] Michelle M. Van Handel *et al.*, *County-level Vulnerability Assessment for Rapid Dissemination of HIV or HCV Infects among Persons who Inject Drugs, United States*, Journal of Acquired Immune Deficiency Syndromes, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5479631/; American Foundation for AIDS Research, *Vermont Opioid Epidemic*, http://opioid.amfar.org/VT.

[141] Vermont Prescription Monitoring System, *Controlled Substance Prescription Histories for Opioid-Related Accidental Fatalities in 2015* at 3, http://www.healthvermont.gov/sites/default/files/documents/2017/01/HSRV_VPMS_10_28_16_opioid_related_accidental_fatality_brief.pdf.

[142] *Id.*

[143] Anne VanDonsel, Shayla Livingston, and John Searles (Vermont Department of Health), *Opioids in Vermont: Prevalence, Risk, and Impact* (October 27, 2016), http://www healthvermont.gov/sites/default/files/documents/2016/12/ADAP_Opioids_Prevalence_Risk_Impact.pdf, at 31 ("Prescription History of Individuals with Opioid-related Accidental Fatalities").

[144] *Opioid-Related Fatalities Among Vermonters, supra* n.133, at 2.

325. Opioid use disorder in pregnant women has become prevalent in Vermont as opioid use has proliferated more broadly, with potentially devastating health consequences for women and their infants. The number of women with diagnosed opioid use disorder at the time of delivery has increased dramatically over time in Vermont: from 0.5 per 1,000 deliveries in 2001 to 48.6 per 1,000 deliveries in 2014—over **seven times** the national average, and the highest among the 30 states that have compiled this data.[145] This widespread prevalence of opioid use disorder in pregnant Vermonters is a major public health concern, because of the serious potential adverse maternal and neonatal outcomes associated with opioid use during pregnancy: preterm labor, stillbirth, neonatal abstinence syndrome, and maternal mortality.[146]

326. The number of infants born in Vermont who are diagnosed with Neonatal Abstinence Syndrome ("NAS")—a condition in which a newborn baby suffers withdrawal symptoms—also far exceeds the national average. Based on available data from 2012, the Vermont Department of Health estimated that the rate of NAS in Vermont was **five times higher** than the national average, and the Vermont statistics have continued to rise.[147]

327. In 2008, there were 17.0 infants with NAS per 1,000 live births (to Vermont residents in Vermont hospitals). By comparison, in 2014, that number had **more than doubled** to 35.3 per 1,000 live births (to Vermont residents in Vermont hospitals).[148]

328. Infants exposed to opioids *in utero* also face serious health consequences. At least 60–80% of these babies will experience symptoms such as seizures, respiratory distress,

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[145] *Opioid Use Disorder Documented at Delivery Hospitalization—United States, 1999-2014*, CDC Morbidity and Mortality Weekly Report (August 10, 2018), https://www.cdc.gov/mmwr/volumes/67/wr/mm6731a1 htm?s_cid=mm6731a1_e, at 847.
[146] *Id.* at 845.
[147] *Opioids in Vermont: Prevalence, Risk, and Impact, supra* n.144, at 44 ("Improved treatment and screening have helped to identify more infants exposed to opioids").
[148] Vermont Department of Health, *Neonates Exposed to Opioids in Vermont* (April 2017), http://www healthvermont.gov/sites/default/files/documents/pdf/ADAP_Opioids_Neonate_Exposure.pdf, at 1.

diarrhea, hypertonia, feeding intolerance, tremors, and vomiting because of their exposure to opioids in the womb.[149]

329. Infants born with NAS require longer and costlier hospital stays than those who are born without exposure to opioids. In 2012, the average length of hospital stay for non-NAS infants born to Vermont residents in Vermont hospitals was 3.0 days, at a cost of $5,590. But Vermont infants with NAS faced hospital stays more than 2 times longer and nearly 3 times more expensive, averaging 7.4 days and $15,456 (respectively).[150]

330. More than 50% of Vermont children under the age of five who have been taken into the custody of the Vermont Department of Children and Families (DCF) have been removed from their homes because of opioid-related issues.[151] As reported in 2016, the reporting of incidences to DCF's Child Protection Line have increased by 30%—from 15,760 reports in 2012 to 20,583 in 2016—and during those same years, approximately 30% of the calls related to substance abuse.[152]

331. Moreover, Vermont's efforts to prevent and treat opioid addiction, and to reduce the overall impact of the opioid epidemic on its citizens, have come at a significant cost to the State.

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[149] Stephen W. Patrick et al., *Neonatal Abstinence Syndrome and Associated Health Care Expenditures*, Journal of the American Medical Association (2012), https://www ncbi.nlm.nih.gov/pubmed/ 22546608.
[150] Vermont Department of Health, *Neonates Exposed to Opioids in Vermont, supra* n.149, at 2.
[151] Vermont Opioid Coordination Council, *Initial Report of Recommended Strategies* (January 2018), http://www healthvermont.gov/sites/default/files/documents/pdf/OCC%202018%20Report%202018-1-9.Final_.pdf, at 3 n.1.
[152] Howard Weiss-Tisman, *Opioid Abuse Continues to Strain Vermont's Child Welfare System*, Vermont Public Radio (December 5, 2017), http://digital.vpr net/post/opioid-abuse-continues-strain-vermonts-child-welfare-system#stream/0; Vermont Dept. for Children and Families Family Services Div., *2016 Report on Child Protection in Vermont*, http://legislature.vermont.gov/assets/Legislative-Reports/Child-Protection-Report-2016.pdf.

332. The demand for opioid addiction treatment has risen dramatically. In 2006, 1,897 Vermonters were treated for opioid use in state-funded treatment facilities. By 2015, that number had **more than tripled**, to 6,084.[153]

333. Opioid overprescribing, misuse, and prescription diversion are draining Vermont's health care system. For example, one study estimated the 2007 total health care spending associated with opioid abuse in Vermont as exceeding $38 million.[154] From 2007 to 2018, opioid prescribing rose dramatically, as did the numbers of persons using, misusing, and abusing both prescription and illegal opioids.

334. The health care costs associated with opioid overprescribing, addiction, and abuse are crushing. Vermont consumers—individuals, employers, and private insurers—have paid millions for opioid prescriptions. Vermont's opioid treatment programs cost more than $70 million between 2012 and 2017 alone.[155] Vermont consumers have likewise borne substantial healthcare costs due to this epidemic of addiction.

335. It is well-established that health care costs for persons addicted to opioids are much higher than health care costs for the general population.[156] For example, overall health care costs are approximately 3 times higher among patients receiving Medication Assisted Treatment for opioid addiction than is true for the general Medicaid population. The average national private payer cost per person with opioid use disorder was $63,356 (in 2015).[157]

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[153] Vermont Department of Health, *People Treated for Opiate Use in Vermont by Fiscal Year*, http://www healthvermont.gov/sites/default/files/documents/2016/12/adap_TotalOpiatebyFY.pdf.
[154] Matrix Global Advisors, *Health Care Costs from Opioid Abuse: A State-by-State Analysis* (April 2015), https://drugfree.org/wp-content/uploads/2015/04/Matrix_OpioidAbuse_040415.pdf, at 5.
[155] Harry Chen, MD (Commissioner, Vermont Dept. of Health), *Status of Opioid Treatment Efforts – Health Reform Oversight Committee* (October 25, 2016), http://www.leg.state.vt.us/jfo/healthcare/Health%20Reform%20Oversight%20Committee/2016_10_25/Status%20of%20Opioid%20Treatment%20Efforts%20-%20Chen.pdf, at 22.
[156] Vermont Department of Health, *The Opioid Addiction Treatment System* (January 13, 2013), http://www.leg.state.vt.us/reports/2013externalreports/285154.pdf, at 9.
[157] *Status of Opioid Treatment Efforts, supra* n.156.

336. The prevalence of opioids in Vermont also places a greater burden on law enforcement—increased costs associated with investigating and prosecuting crimes related to opioid use and abuse, as well as increased costs for treating incarcerated residents for opioid use disorder.

337. The costs of incarceration—which include Medication Assisted Treatment for addiction and other related costs—are largely paid by the State. Crimes associated with prescription drugs—chiefly robbery and burglary—have risen.[158] Data collected by the Vermont Intelligence Center show that law enforcement consistently averages between one and two seizures of illicit opioids per day. In a small state like Vermont, this steady drumbeat of opioid seizures has become a focal point of police time and attention.

V. Defendants Fraudulently Concealed Their Unlawful Conduct.

338. Defendants misrepresented their conduct with respect to promoting opioids and their compliance with their legal obligations to monitor and prevent diversion. These actions misled Vermont and the public—preventing the State, through the exercise of reasonable diligence, from discovering the facts essential to its claims.

A. Cardinal concealed its failure to comply with its duty to prevent diversion.

339. In December 2006, Cardinal agreed to pay $11 million to settle an investigation by the New York Office of the Attorney General over Cardinal's secondary market trading of prescription drugs. As part of the settlement, Cardinal vowed to undertake a series of reforms to its distribution business, including maintaining "a comprehensive compliance manual addressing means to prevent and detect diversion and assure the safety and integrity of prescription pharmaceuticals." Cardinal also agreed to:

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[158] Vermont Department of Health, *Issue Brief: Prescription Drug Misuse in Vermont*, at 12 (Feb. 12, 2013), http://thehungryheartmovie.org/wp-content/uploads/2013/09/SEOW_Rx_Issue_Brief_Final_02_12_13.pdf.

> gather, monitor, and analyze sales data to detect instances of possible diversion of prescription pharmaceuticals, . . . including sales volume, volume changes over time or other significant changes in purchasing patterns, purchases of frequently diverted products, consistency with the customers' business … and any other available relevant information.[159]

340. Less than two years later, in September 2008, Cardinal agreed to pay $34 million to settle an investigation by seven U.S. Attorney's Offices and the DEA over Cardinal's failure to comply with its diversion prevention duties. As part of the settlement, Cardinal vowed to "[m]aintain a compliance program designed to detect and prevent diversion of controlled substances," including procedures to review orders by trained employees to determine whether the order is suspicious and should be cancelled and reported to the DEA, and "[r]eview distributions of [opioids] to retail pharmacy customers and physicians" and identify and investigate any customer that has exceeded Cardinal's distribution thresholds.[160]

341. Cardinal proffered that, over the previous year, it had "invested more than $20 million to significantly enhance its controls across its network to prevent the diversion of controlled substances …. Specifically, the company has expanded its training, implemented new processes, introduced an electronic system that identifies and blocks potentially suspicious orders pending further investigation, and enhanced the expertise and overall staffing of its pharmaceutical distribution compliance team."[161]

342. In 2012, Cardinal entered into a settlement with the DEA to resolve an investigation into its distribution center in Florida. As part of the settlement, Cardinal vowed to "maintain a compliance program designed to detect and prevent diversion of controlled

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[159] New York Office of the Attorney General Assurance of Discontinuance (Dec. 26, 2006) at 14, https://ag.ny.gov/sites/default/files/press-releases/archived/Assurance%20of%20Discontinuance.pdf.
[160] Settlement and Release Agreement and Administrative Memorandum of Agreement, Sept. 30, 2008, CAH_MDL2804_01444908 at 3–5.
[161] Press Release, Cardinal Health Resolves Controlled Substance License Suspension (Oct. 2, 2008), https://cardinalhealth mediaroom.com/newsreleasearchive?item=122576.

substances as required under the CSA and applicable DEA regulations."[162] Cardinal also vowed to "commence procedures to ensure that any pharmacy, chain or retail, placing orders of controlled substances … that Cardinal knows or should know are suspicious in nature, given the totality of the circumstances, will receive a site visit or an anonymous site inspection by a Cardinal employee or a qualified third-party inspector to provide an independent assessment of whether that customer's orders are being diverted."[163]

343. That same year, Cardinal issued a press release touting its anti-diversion system, claiming that the company has "robust controls and performs careful due diligence." Specifically, Cardinal described its system as follows:

> The company's controls feature a system of advanced analytics and teams of anti-diversion specialists and investigators to identify red flags that could signal diversion. When the company's program raises a red flag, its teams immediately investigate. Cardinal Health's anti-diversion specialists use their professional judgment and expertise to determine the appropriate action.[164]

344. Cardinal wrote that it "spent millions of dollars" to build its monitoring system,[165] and assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[166]

345. In a 2017 document published to shareholders, Cardinal acknowledged its role in "maintaining a vigorous program to prevent opioid pain medications from being diverted to improper uses."[167] During an earnings call that same year, George Barrett, Cardinal's Chairman

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[162] Administrative Mem. of Agreement between DEA and Cardinal at 3, CAH_MDL2804_02465982.
[163] *Id.*
[164] Press Release, Cardinal Health Inc. Seeks Restraining Order to Avoid Disruption in Controlled Medicine Shipments from Florida (Feb. 3, 2012), https://cardinalhealth.mediaroom.com/newsreleasearchive?item=122803.
[165] Press Release, Cardinal Health Statement in Response to Preliminary Injunction Hearing: February 29, 2012, https://cardinalhealth mediaroom.com/newsreleasearchive?item=122811.
[166] Bernstein, Lenny, *et al.*, *How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: No One Was Doing Their Job*, Wash. Post (Oct. 22, 2016), https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story html?utm_term=.b5b04da86c80.
[167] Cardinal Health Proxy, Form 14A at 9 (filed Oct. 23, 2017).

and then-CEO, vowed to "operate a very strong, robust, suspicious order monitoring system and process that not only meets [] regulatory requirements," but also "exceeds what is required of distributors."[168]

346. In a subsequent 2017 earnings call, Cardinal stated: "[W]e have spent nearly a decade continuously enhancing our best-in-class suspicious order monitoring tools and analytics to keep pace with the ever-changing shape of the crisis .... We ... take very seriously our responsibilities to serve our health care system. Our anti-diversion systems and controls are substantial, they are well-funded and they are best-in-class."[169]

347. To this day, Cardinal continues to publicly portray itself as "committed to fighting opioid addiction and misuse."[170] Cardinal's website holds the company out as an "industry leader" that uses "constantly adaptive, rigorous systems supported by program specialists who monitor and investigate suspicious orders using advanced analytics and other tools."[171]

348. Cardinal was aware that all of these public promises about what it purported to be doing with its compliance program and its efforts to address the opioid crisis did not align with its actions. Through its repeated statements, Cardinal fraudulently concealed its misconduct—violations of its obligations to monitor and prevent diversion.

B. McKesson concealed its failure to comply with its duty to prevent diversion.

349. Similarly, McKesson has publicized the quality of its anti-diversion efforts since 2005, claiming that it "focuses intensely on ... systems and processes that enable full compliance with the laws and regulations that govern [its] operations .... [because it is] especially aware of

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[168] Cardinal Health Quarterly Earnings Call Tr. at 22 (Aug. 2, 2017).
[169] Cardinal Health Quarterly Earnings Call Tr. at 4–5 (Nov. 6, 2017).
[170] Cardinal, Cardinal Health Opioid Action Program, https://www.cardinalhealth.com/en/about-us/corporate-citizenship/opioid-action-program html (last visited Feb. 24, 2019).
[171] Cardinal, Addressing the Opioid Crisis, https://www.cardinalhealth.com/en/about-us/corporate-citizenship/ethics-and-governance/board-engagement-and-governance.html (last visited Feb. 24, 2019).

[its] responsibility to maintain the integrity of the pharmaceutical supply chain and consumer and patient safety."[172]

350. In May 2008, McKesson entered into a settlement to resolve a DEA investigation over its failure to maintain effective controls at distribution centers in six states. As part of the settlement, McKesson vowed to "maintain a compliance program designed to detect and prevent diversion of controlled substances" and review orders that "exceed established thresholds and criteria" to determine whether the orders were suspicious and "should not be filled and reported to DEA."[173] McKesson also vowed to "follow the procedures established by its Controlled Substance Monitoring Program."[174]

351. McKesson subsequently reassured the public in 2016 that it "put significant resources towards building a best-in-class controlled substance monitoring program to help identify suspicious orders and prevent prescription drug diversion in the supply chain."[175] And McKesson claimed it is "deeply passionate about curbing the opioid epidemic in our country."[176]

352. McKesson continued to hold itself out as committed to preventing diversion, assuring the public in 2017 that it is "doing everything [it] can to help address [the opioid] crisis in close partnership with doctors, pharmacists, government and other organizations across the

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[172] McKesson Corporate Citizenship Report 2005, https://www.slideshare.net/finance2/mckesson-corporate-citizenship-report-74m-2005.

[173] Settlement and Release Agreement and Administrative Mem. of Agreement at 3–4 (May 2, 2008), https://www.dea.gov/sites/default/files/2018-06/Pharmaceutical%20Agreements%20-%20McKesson%20-%202008_0.pdf.

[174] Administrative Mem. of Agreement between McKesson and DEA at 3 (Jan. 17, 2017); https://www.dea.gov/sites/default/files/2018-06/Pharmaceutical%20Agreements%20-%20McKesson%20-%202017_0.pdf.

[175] Higham, Scott, *et al.*, *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post (Dec. 22, 2016), https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html?utm_term=.b40d6961d1df.

[176] Higham, Scott, *et al.*, *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, Wash. Post (Dec. 22, 2016), https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527-949c5893595e_story.html?utm_term=.b40d6961d1df.

supply chain."[177] McKesson also claimed it "invested millions of dollars to build a first class Controlled Substance Monitoring Program [], allowing the company to monitor suspicious ordering patterns, block the shipment of controlled substances to pharmacies when certain thresholds are reached, report suspicious orders to the DEA, and educate customers on identifying opioid abuse."[178]

353. Also in 2017, as part of an agreement with the Department of Justice and DEA to resolve an investigation into some of McKesson's distribution centers, McKesson vowed to "maintain a compliance program intended to detect and prevent diversion of controlled substances."[179] Specifically, McKesson vowed to make specific staffing and organizational improvements to ensure rigorous compliance and eliminate conflicts of interest, maintain customer due diligence files, refrain from shipping suspicious orders, increase customer thresholds only through an established regulatory review process, and conduct periodic auditing.

354. To this day, McKesson continues to tout its commitment to preventing diversion, claiming that it "uses sophisticated algorithms designed to monitor for suspicious orders." McKesson also claims to have "developed a cutting-edge controlled substances threshold management program, using complex and dynamic data analytics."[180]

355. Through these public promises about what McKesson purported to be doing with its compliance program and its efforts to address the opioid crisis, all of which were knowingly in contradiction to the actual facts, McKesson fraudulently concealed its misconduct—violations of its obligations to monitor and prevent diversion.

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[177] Morgenson, Gretchen, *Hard Questions for a Company at the Center of the Opioid Crisis*, NY Times (July 21, 2017), https://www nytimes.com/2017/07/21/business/mckesson-opioid-packaging.html.
[178] *McKesson Announces Preliminary Voting Results From 2017 Annual Meeting of Stockholders* (July 26, 2017), https://www.businesswire.com/news/home/20170726005746/en/.
[179] Administrative Mem. of Agreement at 5 (Jan. 17, 2017), https://www.justice.gov/usao-nj/press-release/file/928636/download.
[180] McKesson's Controlled Substance Monitoring Program, https://www.mckesson.com/about-mckesson/fighting-opioid-abuse/controlled-substance-monitoring-program (last visited Feb. 24, 2019).

C. Defendants concealed their marketing and promotion of prescription drugs.

356. As recently as 2018, at a hearing on "Combatting the Opioid Epidemic: Examining Concerns About Distribution and Diversion," Cardinal's Chairman testified before Congress that Cardinal does not market any medications to patients, a statement now known to be deceptive. As detailed in Section III.A.1 *supra*, Cardinal has run marketing programs for drug manufacturers—including promoting opioids—for many years. Cardinal's Chairman also testified that opioid prescriptions are written by healthcare providers and filled by pharmacies, suggesting distributors have no role in this decision-making process. He claimed that, "[a]s an intermediary in the pharmaceutical supply chain, Cardinal Health does not ultimately control either the supply of or the demand for opioids."[181] However, as detailed in Section III.A.1 *supra*, Cardinal has worked for years to drive increased demand for opioids through its marketing programs.

357. These misstatements are emphasized on the Cardinal website, where the company styles itself a transporter of prescription medications, responsible for secure delivery, and claims that it does not promote prescription medications to members of the public.

358. At the same Congressional hearing, McKesson's Chairman likewise testified that McKesson does not market prescription drugs to doctors or patients, nor "any particular category of drugs, such as opioids, to pharmacies."[182] The State now knows this to be deceptive. As discussed in Section III.B *supra*, McKesson markets prescription drugs to pharmacies through multiple programs and to consumers through the Pharmacy Information Program. McKesson's Chairman also testified that the company does not ship prescription drugs absent a pharmacy

[181] Testimony of George S. Barrett, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, United States House of Representatives, May 8, 2018.
[182] Testimony of John Hammergren, Chairman, President, and Chief Executive Officer McKesson Corporation, Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, United States House of Representatives, May 8, 2018.

order.[183] However, McKesson has, in the past, auto-shipped opioids to pharmacies, through one of its marketing programs, as detailed in Section III.B.1.

359. Defendants' trade lobbying association, HDA, has also falsely denied that Defendants marketed opioids. In publicly denying distributors' role in the opioid epidemic, HDA stated: "Distributors have no ability to influence what prescriptions are written. The fact is that distributors don't make medicines, **market medicines**, prescribe medicines or dispense them to consumers."[184]

360. Defendants' deceptive and misleading public statements, including to the U.S. House of Representatives Oversight Committee, were intended to and did conceal their conduct, preventing the State of Vermont from discovering facts essential to its claims.

D. Defendants fought to safeguard the market for opioids, further ensuring that their misconduct remained concealed.

361. Defendants spent millions of dollars to protect the market for opioids and ensure their misconduct remained concealed.

362. From 2008 through 2018, Defendants' lobbying expenditures increased, corresponding with the increase in opioid use and abuse. To further their interests, including decreased enforcement, Cardinal spent $19.17 million and McKesson spent $17.27 million on lobbying during these deadly years. Meanwhile, law enforcement actions related to opioids declined—civil case filings by the DEA against distributors, manufacturers, pharmacies, and doctors dropped from 131 in fiscal year 2011 to just 40 in fiscal year 2014.[185]

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[183] *Id.*

[184] HDA Press Release, *HDA Statement On Attorneys General Opioid Investigations*, Sept. 19, 2017, https://www.prnewswire.com/news-releases/hda-statement-on-attorneys-general-opioid-investigations-300522358.html

[185] *See* Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post (Oct. 22, 2016), https://www.washingtonpost.com/investigations/the-dea-slowedenforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story html?utm_term=.e2d89d4ccd07.

363. Cardinal and McKesson also worked with trade associations and other organizations. Chief among them is their powerful lobbying association: HDA.

364. Defendants are members of HDA, and Defendants' executives have long maintained leadership positions in HDA's management. These privileged and powerful positions have enabled Defendants to influence the agendas pushed by the trade association.

365. Paul Julian, who was an Executive Vice President and Group President at McKesson, was chairman of HDA from 2008 to 2010, on the HDA Board of Directors from 2000 to 2013, and on its Executive Committee from 2005 to 2013. For his service in furthering distributors' agendas, Julian received HDA's Nexus Award for Lifetime Achievement in 2015. While President of McKesson, Mark Walchirk served on HDA's Board of Directors and Executive Committee for multiple years, beginning in 2014. Layne Martin currently serves on the HDA Research Foundation's Board of Directors in addition to his duties as Vice President and General Manager of Supply Chain Solutions at McKesson.

366. Cardinal senior executives also have served as HDA leaders. While employed as CEO of Cardinal's Medical Segment, Jon Giacomin concurrently served as the Vice Chairman of the HDA Board of Directors from 2014 to 2016, and as its Chairman from 2016 to 2017. Cardinal's Executive Vice President of Global Sourcing, Craig Cowman, currently serves on the HDA Research Foundation's Board of Directors. And Cardinal's current CEO, Mike Kaufman, is a former member of HDA's Board of Directors as well as its Executive Committee.

367. In addition to maintaining leadership positions in HDA, Defendants made significant financial contributions to the association. In 2017 alone, McKesson paid about [redacted] to HDA for dues and other expenses. McKesson [redacted] Also in 2017,

Cardinal and McKesson each contributed $1,161,667 for HDA's Education and Communications Campaign.

368. Part of HDA's stated mission was to prevent [redacted]—legislation that could have brought Defendants' misconduct to light much sooner. [redacted][186]

369. Not surprisingly then, by 2014, HDA had a state government affairs budget of almost [redacted]

370. In 2016, HDA submitted an amicus brief to the United States Court of Appeals in *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017). In the brief, the HDA represented that Cardinal and McKesson "take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that is available to them in the ordering process."[187]

371. Significantly, while acknowledging distributors' duties regarding suspicious orders, HDA also requested the Court of Appeals to limit those duties. HDA asked the court to renounce "any attempt to impose additional obligations on [Defendants] to investigate and halt suspicious orders."[188] The court rejected HDA's arguments. *Id.* at 222–223.

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[186] Deposition of Joseph Ganley, July 27, 2018, MCK-AGMS-032-0000550 at 118-119; MCK-AGMS-032-0000878 at 4.
[187] Brief for Healthcare Distribution Alliance and National Association of Chain Drug Stores as Amici Curiae in Support of Neither Party, *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017) (No. 15-1335), 2016 WL 1321983 at *25.
[188] *Id.* at *26.

372. In addition to its own matters, HDA supported the activities of other front groups. It was a member of the Pain Care Forum, a lobbying consortium that spent more than $880 million from 2006 through 2015 on campaign contributions and lobbying expenses at the state and federal level in an effort to increase the flow of dangerous opioids to consumers. From 2007 to 2014, the number of registered lobbyists in Vermont employed by members of the Pain Care Forum ranged from 16 to 29.

373. The Pain Care Forum lobbied both state and federal governments to prevent restrictions on opioid prescribing. For example, the group paid a PR consultant to draft patient testimonials to encourage the state medical boards to adopt more lax guidelines on opioid dosage. According to reporting by the Associated Press and the Center for Public Integrity, as early as 2008, the Pain Care forum was developing a strategy to "inform the process" at FDA, generating 2,000 comments opposing new barriers to opioids. According to the article, the Pain Care Forum has, for over a decade, met with some of the highest-ranking health officials in the federal government, while quietly working to influence proposed regulations on opioids and promote legislation and reports on the problem of untreated pain. The group is coordinated by the chief lobbyist for Purdue Pharma, the maker of OxyContin. From 2006 through 2015, participants in the Pain Care Forum spent over $740 million on lobbying.

374. Through these efforts, Cardinal and McKesson not only concealed their own misconduct in marketing and promoting opioids and failing to comply with their duties to prevent diversion, but actively lobbied against increased regulation of the opioids market and enforcement of existing laws and regulations, for the purpose of protecting their lucrative market and ensuring that their wrongdoing did not come to light.

CAUSES OF ACTION

COUNT I
Unfair Acts and Practices
Violations of the Vermont Consumer Protection Act

375. The State realleges and incorporates by reference each of the allegations contained in all paragraphs of this Complaint, as though fully set forth herein.

376. Defendants engaged in unfair acts or practices in commerce, in violation of the Vermont Consumer Protection Act, 9 V.S.A. § 2453(a), by:

- Transporting and selling opioids in the State of Vermont while failing to comply with their duties, under federal and state law, to detect, prevent, and report diversion of opioids to other than legitimate channels, including by:
    - Designing suspicious order monitoring programs that failed to monitor, identify, report, and prevent fulfillment of suspicious orders by, *inter alia*, utilizing inflated order thresholds that failed to account for known characteristics of suspicious orders, allowing for manipulation of order thresholds by and/or for the benefit of pharmacy customers, and failing to require adequate investigations of pharmacies; and
    - Failing to adhere to the terms of their suspicious order monitoring programs by, *inter alia*, assigning inadequate staffing to compliance responsibilities, conducting inadequate due diligence of their customers, raising customers' order thresholds without conducting an appropriate investigation, and exempting chain pharmacies from important aspects of the anti-diversion programs;
- Advertising and promoting opioids in the State of Vermont, for the purpose of increasing sales, while failing to design and maintain effective systems to detect, prevent, and report diversion of opioids to other than legitimate channels—as required by federal and state law;
- Disseminating advertising and promotional messages in the State of Vermont that failed, despite the known, serious risks of addiction and adverse effects posed by opioids, to present a fair balance of benefit and risk information; and
- Promoting the initiation of opioid use and/or long-term continuation of opioid use by providing Savings Cards to reduce patients' out-of-pocket expense for these drugs.

377. These acts or practices may be deemed "unfair" in that they offend public policy reflected in (a) established legal standards that require the truthful and balanced marketing of

prescription drugs; and (b) Vermont and federal law, which require licensed wholesale distributors of controlled substances to take steps to combat drug abuse, to regulate legitimate and illegitimate traffic in controlled substances, and to detect, prevent, and report diversion of controlled substances to other than legitimate channels. *See* 20-4 Vt. Code R. § 1400, Part 17; the Controlled Substances Act, 21 U.S.C. § 801, *et seq.*, and its implementing regulations.

378. These acts or practices were unfair because they represented a dereliction of the Defendants' duties to monitor, prevent, and report diversion of the dangerous and addictive opioids that they sold in the State. Defendants understood that they had a critical role in the federal- and state-mandated system to prevent diversion, and that they were responsible for not sending more opioids into Vermont communities than were reasonably necessary to meet legitimate demand for medical use. However, their financial interests were best served by (1) increasing sales of these expensive and profitable drugs, and (2) avoiding damage to customer relationships (and potential loss of market share) that could result from holding or investigating suspiciously-high orders. Defendants chose to prioritize their financial interests ahead of consumer health and safety, designing and implementing ineffective diversion control systems, and marketing and promoting opioids on behalf of their manufacturer clients. This conduct is immoral, unethical, oppressive, and unscrupulous.

379. By reason of Defendants' conduct, Vermont consumers have suffered substantial injury by reason of the health risks associated with opioid abuse and misuse, including the pain and suffering associated with opioid addiction, injury, disability, overdose, and death, as well as the associated financial costs.

COUNT II
Deceptive Acts and Practices
Violations of the Vermont Consumer Protection Act

380. The State realleges and incorporates by reference each of the allegations contained in all paragraphs of this Complaint, as though fully set forth herein.

381. Defendants engaged in unfair and deceptive trade practices in commerce, in violation of the Vermont Consumer Protection Act, 9 V.S.A. § 2453(a), by making material misrepresentations and omissions regarding the risks and benefits of its opioid products, including by:

- Making and disseminating false or misleading statements about the benefits, risks, and diversion-potential of opioids; and
- Making statements to promote the use of opioids that omitted or concealed material facts, including the risks of diversion and misuse, dependence, addiction, overdose, and death associated with these drugs.

382. Defendants' material omissions rendered even seemingly truthful or neutral statements about opioids false and misleading, because they were materially incomplete. At the time Defendants made these statements and disseminated these promotional materials, Defendants failed to include material facts about the risks and benefits of opioid use and failed to provide "fair balance," as required by law.

383. These misrepresentations and omissions were likely to mislead the prescribers and pharmacists to whom they were directed, affecting their decisions regarding the prescribing, dispensing, and use of opioids. The meaning Plaintiff ascribes to Defendants' misrepresentations herein is reasonable, given the nature thereof.

COUNT III
Negligence

384. The State incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

385. Defendants have a duty under the common law of Vermont to exercise the degree of care that a reasonably prudent person would under the circumstances. The scope of this common law duty of ordinary care expands according to the foreseeability of the consequences of a defendant's acts or omissions.

386. Defendants distribute large quantities of addictive prescription opioid narcotics, which have been designated as controlled substances under state and federal law. It is foreseeable that Defendants' failure to design and operate effective controls to monitor, identify, report, and prevent the fulfillment of suspicious orders of prescription opioids would create a risk of abuse, misuse, and injury to the State and its citizens. The very purpose of state and federal laws regulating Defendants' activities is to prevent the abuse of controlled substances and to prevent the diversion of those substances. Thus, Defendants have a common law duty to prevent the diversion of controlled substances into illegitimate channels.

387. This common law duty of care is fully supported by and incorporates State laws governing distributors of controlled substances, which impose a statutory duty on such distributors to provide effective controls and procedures to guard against diversion. The statutory duty includes the explicit requirements that a distributor must: (a) design and operate a system to identify suspicious orders of controlled substances; (b) report the identification of all suspicious orders of controlled substances; and (c) exercise sufficient diligence to prevent the fulfillment of any suspicious orders. 26 V.S.A. § 2068; 20-4 Vt. Code R. § 1400:17.25 (incorporating the security requirement set forth under federal law).

388. State laws regulating the distribution of controlled substances are "safety statutes" under Vermont law, the violation of which gives rise to a rebuttable presumption of negligence.

389. Defendants breached their common law and statutory duties by failing to maintain effective controls over prescription opioids by, *inter alia*, the following acts and omissions:

- creating ineffective anti-diversion and suspicious order monitoring systems that utilized inflated order thresholds that failed to account for known characteristics of suspicious orders, allowed for manipulation of order thresholds by and/or for the benefit of pharmacy customers, and failed to require adequate investigations of pharmacies;
- failing to effectively implement their anti-diversion programs, including by assigning inadequate staffing to compliance responsibilities, conducting inadequate due diligence of their customers, raising customers' order thresholds without conducting an appropriate investigation, and applying, different, even looser rules to their chain pharmacy customers;
- failing to report to the proper authorities all suspicious orders identified by their own monitoring protocols; and
- failing to prevent the shipment of suspicious orders by, among other things, failing to conduct proper diligence prior to filling suspicious or potentially suspicious orders.

390. Defendants' breach of their duties fueled the widespread circulation of opioids into illegitimate channels in Vermont. The structure of Vermont's controlled substances regulations—and of the federal regulations incorporated by Vermont law—acknowledges that preventing the abuse, misuse, and diversion of controlled substances can only occur where every participant in the distribution chain maintains effective controls. Defendants' failure to satisfy their duties to monitor, identify, report, and prevent the fulfillment of suspicious orders for prescription opioids has caused or substantially contributed to the abuse, misuse, and diversion of those opioids. Had Defendants effectively carried out their duties, opioid abuse, misuse, diversion, and addiction would not have become so widespread in Vermont, and the costs borne by the State in addressing and abating the opioid epidemic would have been averted or much less severe.

391. The State has expended millions of dollars in addressing and attempting to abate a wide-spread public health epidemic that has been fueled by the drugs that Defendants sent into Vermont. These expenses are the foreseeable and proximate result of Defendants' failure to design and implement effective diversion controls in accordance with their legal duties. A reasonably prudent distributor of controlled substances would foresee that failing to maintain effective controls against the diversion of highly addictive narcotics would fuel over-prescription, would lead to overpayment by payors, and would result in the attendant costs of addressing an opioid crisis.

392. As a direct result of Defendants' misleading representations regarding their purported compliance with their duties to prevent diversion, the State was unaware of, and could not reasonably know or have learned at an earlier time through reasonable diligence, the risks described herein.

COUNT IV
Public Nuisance

393. The State incorporates by reference the preceding paragraphs of this Complaint as if fully set forth herein.

394. Defendants, through their actions described throughout the Complaint, have created—or were a substantial factor in creating—a public nuisance by unreasonably interfering with a right that is common to the general public.

395. The State and its citizens have a public right to be free from the substantial injury to public health, safety, peace, comfort, and convenience that has resulted from Defendants' actions and omissions.

396. Defendants have interfered with the above enumerated right by creating a long-lasting and continuing public nuisance through distributing prescription opioids that they knew,

or reasonably should have known, were being overprescribed, misused, or abused while illegally failing to maintain appropriate controls over such distribution. By causing or substantially contributing to the opioid crisis in Vermont, Defendants have created an unreasonable public nuisance. Without Defendants' actions, opioid use would not have become so widespread in Vermont, and the opioid epidemic which the State now faces would have been averted or would be much less severe.

397. As a direct and proximate result of Defendants' actions and omissions, the State and its citizens suffered harms including, *inter alia*, the following:

- Normalization of over-prescribing and over-dispensing of prescription opioids by prescribers and pharmacists in the State;
- Increased availability and sales of prescription opioids, accompanied by increased diversion;
- Dependence and addiction to prescription opioids leading to escalation to non-prescription or "street" opioids such as heroin and fentanyl;
- Higher rates of opioid misuse, abuse, injury, overdose, and death, and their impact on Vermont families and communities;
- Heightened rates of opioid use disorder in pregnant women and resulting neonatal abstinence syndrome in their children;
- Increased health care costs for individuals, families, employers, and the State; and
- Greater demand for law enforcement, including the costs of treating prisoners with addiction.

398. Public resources have been, and are being, consumed in efforts to address the opioid epidemic, reducing the available resources that could be used to benefit the Vermont public at large.

399. At all times relevant, Defendants controlled the instrumentalities of the nuisance: distribution channels that moved prescription opioids from manufacturers to pharmacies in the

State and the systems (or lack thereof) for monitoring and identifying suspicious orders of prescription opioids and the protocols for halting, investigating, and reporting those orders.

400. At all times relevant, Defendants knew that prescription opioids are regulated controlled substances that have a high potential for abuse and may lead to severe psychological or physical dependence. Defendants were further aware—because they helped create it—that a national opioid epidemic had led to widespread addiction, overdoses, hospitalizations, and fatalities. The harms alleged herein were therefore foreseeable to Defendants as a direct and proximate result of their actions and omission. It was unreasonable for them to move prescription opioids from manufacturers to pharmacies and other dispensaries without systems in place to detect, investigate, halt, and report suspicious orders. It was also unreasonable for Defendants to fail to design and operate a system that would disclose the existence of suspicious orders of prescription opioids and to fail to report, investigate, and halt those orders, as required under Vermont law.

401. Defendants' actions and omissions were a material element in allowing prescription opioids to become available throughout the State on an unnecessary and dangerously large scale.

402. As a direct result of Defendants' misleading representations regarding their purported compliance with their duties to prevent diversion, the State was unaware of, and could not reasonably know or have learned at an earlier time through reasonable diligence, the risks described herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff State of Vermont respectfully requests the Court enter judgment in its favor and the following relief:

(A) A judgment in the State's favor and against Defendants on each cause of action asserted in the Complaint;

(B) With respect to Counts I and II, a permanent injunction prohibiting Defendants from engaging in the unfair and deceptive acts and practices described in the Complaint;

(C) With respect to Counts I and II, a judgment requiring Defendants to disgorge all funds acquired or retained as a result of any acts or practices found to be unlawful;

(D) With respect to Counts I and II, statutory penalties of $10,000 for each violation of the Vermont Consumer Protection Act;

(E) With respect to Count III, all damages allowable under common law;

(F) With respect to Count IV, an order providing for abatement of the nuisance that Defendants created or were a substantial factor in creating, enjoining Defendants from further conduct contributing to the nuisance, and damages as compensation for funds the State has already used to abate the nuisance;

(G) The award of investigative and litigation costs and fees, including attorneys' fees, to the State; and

(H) Such other, further, and different relief as this Court may deem appropriate.

JURY TRIAL DEMANDED

The State demands a trial by jury.

Dated: March 26, 2019

Respectfully submitted,

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